SWELL24

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SWELL 24: SLEEP WELL 24

Informed Consent Form to Participate in Research (Older Adults)
Dr. Jaime Hughes, PhD, MPH, MSW, Principal Investigator

SUMMARY

You are invited to participate in a research study. The purpose of this research is to understand how older adults' daytime and nighttime activities impact sleep health and to evaluate whether a sleep health program addressing daytime *and* nighttime activities helps to improve older adults' sleep and daytime function.

You are invited to be in this study because you responded to the survey, *How Are You Sleeping?* Some of your responses indicated you may have sleep problems.

This research study is divided into two different parts. Your participation may include only one of these two parts, or both. Part I of this study includes an in-person sleep-health assessment and guided conversation about your sleep habits and preferences. Part II includes a four-session sleep health program to develop healthy sleep and activity behaviors. Each part of the research study is described in the following pages.

Participation in this study will involve up 52 older adults across the two parts of this study. Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. There may be other choices available to you. Your primary care doctor may be able to discuss other options with you. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

Being in this study involves minimal risk/inconvenience to you. The risk of harm or discomfort that may happen because of taking part in this research study is not expected to be more than in daily life or from routine physical or psychological examinations or tests.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study please contact Dr. Jaime Hughes, Principal Investigator, at [redacted]

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted] or the Wake Forest University Health Sciences Research Subject Advocate at [redacted]

INTRODUCTION

You are invited to be in a research study. Research studies help scientists learn new information that may help other people in the future. You are being asked to be in this study because you are at least 65 years old, receive primary care services through an Atrium Health Wake Forest Baptist Health primary care clinic, and live near Atrium Health Wake Forest Baptist Medical Center. You also indicated some sleep problems on the *How Are You Sleeping?* Survey.

Your participation is voluntary. You do not have to be a part of this study if you do not want to. Please take your time in making your decision if you would like to join. Ask your doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to develop a comprehensive sleep-activity program for older adults.

- Understand older adults' sleep-activity behaviors, including how these behaviors are related to overall health and daytime function
- Explore older adults' and providers' knowledge, beliefs, and attitudes around screening and treating sleep problems
- Evaluate whether a sleep health program to promote healthy nighttime sleep ***and*** healthy daytime activity improve older adults' sleep and function

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Up to a total of 52 older adults total will take part in this study: Up to 40 older adults will complete a sleep-health assessment (Part I) and up to 12 adults will participate in the sleep health program (Part II). All participants will be enrolled at this site. In order to identify the 12 participants subjects needed for Part II, we may need to screen as many as 25 older adults because some people will not qualify to be included in the study or will chose not to participate.

WHAT IS INVOLVED IN THE STUDY?

This study will take place in two parts. Each part is described below. You may either participate in Part I or Part II, or both. A member of the research team will tell you which part(s) you will participate in.

Part I includes a two-part visit to observe your sleep and activity behaviors. At the first visit, you will be asked some basic questions about your overall health and function. You will also be provided with a sleep-activity watch (similar to a sports watch) that you will be asked to wear for up to 6 days and 5 nights. You will also be asked to complete a daily diary while you wear the watch. You will be asked to complete a series of brief questions immediately after you wake up each morning and another set of questions just before you go to bed at night. You may also be asked to complete some questions throughout the day. You will be asked to return to the clinic approximately one week later. At this second visit, you will be asked questions about your nighttime sleep and daytime activities. You will also be asked to return the sleep watch to the study team at your second visit. At each visit, you will also be asked a series of brief questions

about your preferences for receiving a comprehensive sleep health program to promote healthy nighttime sleep behaviors and healthy daytime activities.

Part II includes a four-session sleep health program to help you improve your nighttime sleep and daytime activity behaviors. You will meet one-on-one or in a small group setting with a health educator or sleep coach four times over four to six weeks. Each session will be approximately 30-45 minutes in length. Each session will include education and personalized coaching on developing healthy nighttime sleep and daytime activity behaviors. Before you start the program, you will be asked to complete some questionnaires about your sleep and activity. You may also be asked to wear a sleep watch for up to 6 days and 5 nights. Throughout the program, you will be asked to record your sleep and activity in either a paper or electronic daily diary. After the program ends, you will be asked to complete the same questionnaires about your sleep and activity. You will also be asked to wear and return the sleep watch to the study team at the end of the program.

WILL YOU BE RECORDED?

If you participate in an interview during this study, your interview will be recorded so that detailed notes can be taken. This is being done so that our team can listen and engage fully while talking with you and then review what was shared during study visits (interviews and sleep health program sessions). Recordings also help our team to improve our process, including how we interact with patients and deliver sessions in the sleep health program. These audiotapes/recordings will be considered Protected Health Information if they contain information that identifies you. You understand that you may request the taping or recording be stopped at any time during the course of the research study. You can also withdraw your consent to use and disclose the audiotape/recording before it is used, but doing so may affect your eligibility to remain in the research study. You should also understand that you will not be able to inspect, review, or approve the audiotapes, recordings or other media (including articles containing such) before they are used in this study.

Please choose one of the following regarding the use and disclosure of the photograph/videotape/audiotape used in this research study:

_____ I would like the audiotapes/recordings of me to be destroyed once their use in this study is finished. I understand that destroying the audiotapes/recordings at the end of this study will not affect any prior use of the photographs/videotapes/audiotapes/recordings.

____ The audiotapes/recordings of me can be kept for use in future studies provided they are kept secure, and any future study will be reviewed by an IRB. I understand that I will not be able to inspect, review or approve their future use.

You can choose to have a copy of your sleep-health assessments at the conclusion of the study. This will include your answers to questions about your sleep, health, and function, as well as results from your sleep watch. We will not send copies of your assessments to your personal

physician. If you would like to receive a copy of your sleep diary results and/or the results of wearing the sleep watch, you may ask a member of the research team to provide this information to you. Please note these results will not be shared until we have finished our research study.

How Long Will I Be in the Study?

This project is expected to last approximately 18 months. Your participation will not be for this full time. Most of your participation will be limited to two months, at most. You can stop participating at any time. If you decide to stop participating in the study, we encourage you to talk to the investigators or study staff first.

What are The Risks of the Study?

Being in this study involves minimal risk/inconvenience to you. You should discuss the risk of being in this study with the study staff. As part of the sleep health program (Part II), you may be asked to adjust your sleep-wake schedule. This may include the amount of time you are active during the day. As you make these adjustments, you may find you feel sleepy during the day. Finally, you will also be asked to record how you're sleeping in a daily sleep diary. Doing so should take less than 5 minutes of your time but some individuals might find this burdensome. The risk of harm or discomfort that may happen because of taking part in this research study is not expected to be more than in daily life or from routine physical or psychological examinations or tests.

Are There Benefits to Taking Part in the Study?

Part I: If you are only participating in the sleep-health assessment portion study, you are not expected to receive any direct benefit from taking part in this research study. We hope the information learned from this study will benefit other people in the future.

Part II: Based on experience giving this sleep health program to older people with insomnia, researchers believe these programs, or behavioral treatments, might benefit individuals with insomnia. The benefits of participating could include better nighttime sleep, more daytime activity, or improved health and functioning. However, because individuals respond differently to treatments, no one can know in advance whether it will be helpful for your particular case.

What Other Choices Are There?

You do not have to be in this study. You should talk to the researchers about all the choices you have. Instead of being in this study, you have the option to talk with your healthcare provider about options for your sleep health. Your sleep problems could be treated with behavioral or medication treatments even if you do not take part in the study. Medication treatments may be the most common alternative for sleep problems. All treatment options may involve some risk. For example, you may experience side effects when taking medication for sleep problems or you may find that medications do not work for you. You should discuss these treatment options and their risks with your doctor.

What Are the Costs?

All study costs, including any study products or procedures related directly to the study, will be

paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required or permitted by law, or necessary to protect the safety of yourself or others.

Your information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

WILL YOUR RESEARCH **DATA** BE CONFIDENTIAL?

A sleep watch is a sportswatch-like device (e.g., Fitbit) that collects information about you throughout the day, including your movement (steps). The device sends the information to an app (or program) on a smartphone or tablet, which then uploads the information to a website. For the purposes of this study, we will use Fitbit as our sleep watch. Our team uses this information to help understand how and when you move during the day. This type of information is helpful so that our team can provide personalized recommendations on your sleep and activity behaviors. We may ask you to use the Fitbit app to help track your activity during the day. Therefore, those

at Fitbit may be able to view your activity and other information and may also be able to view roughly where the smart device using the Fitbit app is in the world. We will not add any of your personal information to your Fitbit account, and we will not ask you to share your Fitbit information with anyone except the study team. We advise against editing your account to include your name or other personal information or using the Fitbit app to share your information as a part of a "challenge', as these activities reduce your privacy.

WILL YOU BE PAID FOR PARTICIPATING?

You will be paid *$25* for each completed, scheduled study visit. This includes visits during which you answer questions about your sleep or health. If you participate in Part I of the project, you may receive up to $50. If you participate in Part II of the project, you may receive up to $75. If you participate in both parts of the study, you may receive up to $125.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by the National Institute on Aging and the Wake Forest University School of Medicine Older Americans Independence Center ("Pepper Center"). The sponsor is providing money or other support to the researchers to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes**:** your name, gender, race/ethnicity, marital status, highest degree, and medical history.

We will take steps to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and Atrium Health Facilities; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy

regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs, videotapes, audiotapes or other recorded media which are identify you unless we you're your written authorization.

Monitors, auditors, IRB or other regulatory agencies will be granted direct access to your medical record for verification of clinical trial procedures or data to the extent permitted by other applicable laws. These monitors, auditors, and other individuals are also required to maintain the confidentiality of your protected health information.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for at least six years after the study is finished. At that time any research information not already in your medical record will either be destroyed or it will be de-identified.

You can tell Dr. Hughes that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Jaime M. Hughes, PhD, MPH, MSW
[redacted]

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study.

If you choose to participate in this study, your medical record at Atrium Health, Wake Forest University Health Sciences, or their respective affiliated entities will indicate that you are enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. Authorization to access this part of the medical record will only be available to people who have a need to know this information in order to perform their job-related duties. If you are not a patient of these

health care facilities, a medical record will be created for you anyway to provide access to this important information to providers in case of an emergency.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this Web site at any time.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because it is in your nest medical interest, new information becomes available, you had an unexpected reaction, you failed to follow study instructions, or because the entire study has been stopped. Information that identifies you may be removed from the data or specimens that are collected as part of this study and could be used for future research or shared with others without additional consent.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study investigator, **Dr. Jaime M. Hughes at [redacted].**

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [redacted] or the Research Subject Advocate at [redacted].

You will be given a copy of this signed consent form.

SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

I am agreeing to participate in the following part of this research study. I understand that I may be asked to sign this form again if I agree to participate in additional parts of this study.

- ☐ Part I: Sleep-Health Assessment
- ☐ Part II: Sleep Health Program

Subject Name (Printed):_____

Subject Signature: _____ Date: _____Time:_____ am pm

Person Obtaining Consent (Printed): _____

Person Obtaining Consent:_____ Date:_____ Time:_____ am pm

By signing below, I agree to participate in additional parts of this study.

- ☐ Part I: Sleep-Health Assessment
- ☐ Part II: Sleep Health Program

Subject Name (Printed):_____

Subject Signature: _____ Date: _____Time:_____ am pm

Person Obtaining Consent (Printed):_____

Person Obtaining Consent:_____ Date:_____ Time:_____ am pm