UPMC
Western Psychiatric Institute and Clinic

CONSENT TO ACT AS A SUBJECT IN A RESEARCH STUDY:
CAREGIVER CONSENT

TITLE: myRhythmWatch (myRW) Application for Persons with Dementia and their Family Caregivers

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OVERVIEW: KEY INFORMATION

Your participation in this study is voluntary. Research studies only include people who choose to participate. Our staff will explain this study to you and will answer any questions you may have. *Please take your time to make your decision about participation.*

Study Purpose: This study will examine the feasibility of a rest-activity rhythm app called myRhythmWatch (myRW) for persons with Alzheimer's Disease and AD-related dementias (ADRD) and their family caregivers.

Study Duration and Procedures: Participation in this study will involve 3 virtual visits (phone call or audio/videoconferencing) over the course of approximately 5 months. Participation will be virtual, using audio/videoconferencing or phone. If needed, some assessments may be completed by in-person or mail.

- Activities that you may be asked to complete include completing questionnaires, wearing an Apple watch, keeping a diary of certain sleep and daytime activities, viewing the myRW app, and weekly phone calls with a sleep/health coach.

Potential Risks/Discomforts:

- Psychological discomfort during study procedures is possible.
- Breach of confidentiality (privacy) is possible but not common.

Potential Benefits:

- There are no guarantees that you will receive any benefit from participating in this study.
- You may benefit from screening procedures that may highlight important aspects of your rest-activity rhythm.
- You may find satisfaction in helping us understand older adults' health behaviors while caring for someone with Alzheimer's Disease and AD-related dementias (ADRD).

Compensation:
You will receive a total of $125 upon completion of the study procedures and return of the Apple watch. You will be compensated $50 for wearing the Apple watch for up to 6 weeks and for completing the baseline (T1) assessment, $50 for completing the 6 week follow up assessment (T2), and $25 for completing the 3 month follow up assessment (T3).

INFORMATION ABOUT THIS FORM

You may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of the study, and the risks and possible benefits of participating in the study. Please take time to review this information carefully.

After you have finished, please talk to the researchers about the study concerning any questions you may have. You may also wish to talk to others (for example, your friends, family, or other doctors) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

PURPOSE OF THIS STUDY

Why is this research being done? The University of Pittsburgh is conducting a research study to test the usability of the myRhythmWatch (myRW) an iOS app that objectively measures the rest-activity rhythm, among dementia patients and their family caregivers. as well as obtain information about user-adherence and obtain user-feedback about the myRW app.

INFORMATION ABOUT STUDY PARTICIPATION (PARTICIPANTS)

Taking part in this study is completely voluntary. You do not have to participate if you don't want to. You may also leave the study at any time, even after signing this form. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your relationship with UPMC, the University of Pittsburgh, or the Alzheimer's Disease Research Center. Your information is kept completely confidential.

Who can take part in this study?
You may be eligible to participate in this study if:

- You are 50 years old or older
- You are providing care for a loved one 60+ years with Alzheimer's disease or AD-related dementia
- You are experiencing depression symptoms
- You experience stress or strain, either physical or emotional, related to caregiving
- The person you're caring for has any problems with sleep or keeping a consistent routine
- You are living with your care recipient
- You are willing to try the myRW app and participate in assessments?

How many people (participants) are expected to take part in this study?
A total of 60 participants are expected to take part in this study: 30 participants who are family caregivers and 30 participants with Alzheimer's Disease (AD) or an AD-related dementia. We aim to recruit approximately 60 participants for this study.

INFORMATION ABOUT STUDY PARTICIPATION (PROCEDURES)

What procedures will be performed for research purposes? How much of my time will be needed to participate?

Individuals will be screened for eligibility by phone. If ineligible, or unable to comply with research procedures, participants will be withdrawn from the study by investigators.

T1 – Baseline Visit (2-3 hours): Once you sign informed consent via eConsent in REDCap or mailed written consent and are enrolled to the study, you will complete several baseline assessments. During the assessments, you will be asked about your physical health, mood, and health behaviors like sleep and daytime activity.

myRW Testing Procedures (0-6 weeks): After the baseline assessment, you will be asked to wear an Apple watch for up to 6 weeks. You will wear the watch for the duration of the 6-week testing period, including during the night, but not while showering or swimming. The watch should not be immersed in water. The Apple watch and myRW app record movement and acceleration intensity like how quickly you are moving. We will provide participants with a

current model Apple Watch and, if you do not own one, an iPhone. We will also provide you with the myRW app on your iPhone. We will introduce you to the features of the Apple watch and myRW app during the virtual/phone baseline visit. We will train you how to use the myRW app. After the 6-week testing period, you will mail the Apple watch back to us in a pre-paid envelope provided to you by the study team. Contactless drop off will also be available by request.

You will also be contacted weekly by phone by a health coach to discuss your rhythm of sleep and daytime activity and personal health goals. Phone calls last approximately 5 – 30 minutes each week.

T2 –Post-testing Assessment (1-2 hours): After completing the 6-week myRW testing period, you will be asked to complete a virtual visit or phone call, where you will complete assessments about mood and health behaviors. You can also discuss your likes and dislikes of the myRW app. Participants will be expected to return all study equipment to the study team by pre-paid mail envelope. Law enforcement may become involved if study equipment is not returned.

T3 - Follow-up Assessment (at 3 months after the post-testing assessment, 1-2 hours): You will be asked to complete a virtual visit or phone call, where you will complete questionnaires about mood, health behaviors, and other lifestyle habits at 3 months after the myRW testing period.

When will I complete my participation in the study?
The myRW testing period is up to 6 weeks. The follow up assessment occurs 3 months after the myRW testing period. The total study time will be approximately 5 months.

INFORMATION ABOUT RISKS AND BENEFITS

What are the possible risks, side effects, and discomforts of this research study?
There are some risks involved in you participating in this study.

Risks of rating scales and questionnaires: Some inconvenience and/or anxiety may occur due to time required to complete formal rating scales and questionnaires. The mood assessments impose some risk of emotional discomfort. You can refuse to answer any questions or questionnaires that make you uncomfortable. Another potential risk associated with your participation is embarrassment or frustration that some people experience when using new technology. This is not unusual, and you will have many occasions to share your views about the watches and app.

Risk of skin irritation or discomfort related to wearing the Apple watch: Skin irritation is rare, but if it occurs, alert a study team member, and discontinue watch use. Sometimes if the watches are too tight (like any watch), it can cause discomfort; we will advise you on how to wear the watch at an appropriate tightness.

Risks of breach of confidentiality of research data: There is a possibility that if your study research data were to become generally known, this knowledge of your research data could potentially impact your future insurability or employability: or have a negative impact on family relationships and/or result in shame or embarrassment. Although every reasonable effort has been taken, confidentiality during Internet communication procedures cannot be guaranteed and it is possible that additional information beyond that collected for research purposes may be

captured and used by others not associated with this study. We will do everything possible to protect your privacy.

The researchers will try to minimize these risks by:
Psychological Discomfort during the Screening Process and Study Procedures: You can end participation at any time if participating in this study leads to significant distress. You may also refuse to answer any questions that make you uncomfortable. Interviews will be carried out by study staff and supervised by Drs. Stahl and Smagula. If study questionnaires or study protocol elicit distress, you will be instructed to contact the PI, who will assist with questions and concerns.

Breach of Confidentiality: As with all research, there is a chance that confidentiality could be compromised. It is possible that information regarding your mental and physical health will be discovered by individuals outside of study personnel, despite careful steps to protect confidentiality. Maintaining strict security on information provided by participants will minimize risks to confidentiality. Study data will be kept strictly confidential, and participants' identities will not be revealed in any publication. All participants will have identification numbers that will be used on forms and for data storage purposes. The study team will have locked files linking participants' names and identification numbers. All information will be kept in locked files and access to these materials will be limited to study personnel. Computer databases and tablet data are protected by several procedures, including password protection of subject data and a firewall around the entire Research Computing Network at the University of Pittsburgh. With your permission, the study team may also send reminders and answer general questions about the study through text message. Text messages are not encrypted or secure during their transmission and could be intercepted by unauthorized third parties.

What are the potential benefits of taking part in this research study?
There are no direct benefits to you for participating in this research study. You may benefit from the satisfaction you may derive from helping us understand how to measure activity patterns, and which activity patterns relate to mood/stress in family caregivers.

CONFIDENTIALITY OF SUBJECT RECORDS

Who will know about my participation in this research study?
Any information about you obtained from or for this research study will be kept as confidential (private) as possible. As a participant, you will be assigned an identification number. This number, instead of your name, will be used to identify the health and activity data that you provide. All health and activity data that you provide will be de-identified in this way and stored in a secure UPMC database. We will keep documents linking your name and identification number stored in locked or password-protected files retained by us for a minimum of seven years. You will not be identified by name in any publication of the research results unless you sign a separate release form giving your permission.

Who will have access to identifiable information related to my participation in this research study?
In addition to the investigators listed on the first page of this consent form and their research staff, the following individuals will or may have access to identifiable information related to your participation in this research study:

- The National Institute on Aging may have access to identifiable data for the purposes of monitoring the appropriate conduct of this study.
- It is possible that authorized representatives from the University of Office of Research Protections may review your data for the purpose of monitoring the conduct of this study.
- In very unusual cases, your research records may be released in response to an order from a court of law. Also, if we learn that you or someone with whom you are involved is in serious danger of potential harm, we will need to inform the appropriate agencies, as required by Pennsylvania law.

To protect your confidentiality, all personal identifiers (such as your name, birth date) will be removed (de-identified) and replaced with a specific code number. The information linking this code number to your identify will be kept in a separate, secure location. The investigators on this study will keep the data indefinitely.

Will my data be shared with others?
All data will be confidential and not shared with other participants. Your deidentified data may be shared with individuals outside of our research team who want to verify our research findings. However, your personally identifiable data will never be shared. De-identified data may be shared with other researchers for use in future studies as well or placed in federal repositories.

Your data used in this research study may contribute to a new discovery or treatment. In some instances, these discoveries or treatments may be of commercial value and may be sold, patented, or licensed by the investigators and the University of Pittsburgh for use in other research or the development of new products. You will not retain any property rights, nor will you share in any money that the investigators, the University of Pittsburgh, or their agents may realize.

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. This website can be searched at any time.

ENDING THE STUDY

Is my participation in this research study voluntary?
Your participation in this study is completely voluntary. You may refuse to take part in it, or you may stop participating at any time, even after signing this form. Your decision will not affect your relationship with UPMC or the University of Pittsburgh.

To formally withdraw from this research study, you should provide a verbal notice to the principal investigator or study team listed on the first page of this form.

If you have questions about this research study, you may contact the investigators listed at the beginning of this consent form. If you have questions about your rights as a research subject, please contact the Human Subjects Protection Advocate at the University of Pittsburgh IRB Office, 1-866-212-2668.

Could the researchers take me out of the study even if I want to continue to participate?
Yes. There are many reasons why the researchers may need to end your participation in the study:

- Your condition changes and you need treatment that is not allowed while you are taking part in the study (e.g., increased suicidal risk)
- The researcher believes that it is not in your best interest to stay in the study
- The study is suspended or canceled
- You do not follow instructions from the researchers
- You may also be withdrawn if the person you are caring for is no longer under your care for any reason (deceased, moves to nursing home/other caregiver, etc).

FINANCIAL INFORMATION

Will who pay for the costs of the study?
Neither you, nor your insurance provider will be charged for the cost of the procedures performed only for the purposes of this research study. You and/or your insurer will be billed in the usual manner for your standard medical care (care you would receive even if you were not participating in this research study.)

Will I be paid if I take part in this research study?
You will receive a total of $125 upon completion of the study procedures and return of the Apple watch. You will be compensated $50 for wearing the Apple watch for up to 6 weeks and for completing the baseline (T1) assessment, $50 for completing the 6 week follow up assessment (T2), and $25 for completing the 3 month follow up assessment (T3).

Payment to participants is considered taxable income regardless of the amount. If a participant receives $600 or more in a calendar year from one organization, that organization is required by law to file a “Form 1099 – Miscellaneous” with the IRS and provide a copy to the taxpayer. We are required to give your name and social security number to the Accounting Office. Participants who do not provide a social security number may still participate in the research, but the IRS requires that a percentage of the payment be sent by the institution to the IRS for ‘backup withholding'.

One or more of the investigators conducting this research has a financial interest in Activity Rhythm Solutions Corporation. This means it is possible that results of this study could lead to personal profit for the individual investigator(s) and/or the University of Pittsburgh. Any questions you might have about this will be answered fully the Human Subject Protection Advocate of the University of Pittsburgh at (866) 212-2668, or by the Principal Investigator, Dr. Sarah T. Stahl, PhD at (412) 624-0422, who has no financial conflict of interest with this research.

VOLUNTARY CONSENT

- The above information has been explained to me and all my current questions have been answered.
- I understand that I am encouraged to ask questions about any aspect of this research study during this study, and that those questions will be answered by the researchers listed on the first page of this form.
- I understand that there is little risk involved in this study.
- I understand that my participation in this study is voluntary and that I am free to refuse to participate or to withdraw my consent and discontinue my participation in this study at any time. My decision to participate will not affect your relationship with UPMC or the University of Pittsburgh.
- I understand that I may contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations if the research team is unavailable.
- I agree to participate in this study. A copy of this consent form will be provided to me.

Participant's Signature: _____

Printed Name of Participant: _____

Date: _____

INVESTIGATOR CERTIFICATION OF INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual, and I have discussed the potential benefits and possible risks of study participation. Any questions the individual has about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

Name of person obtaining consent: _____

Signature of person obtaining consent: _____

Role in study: _____

Date: _____