RUSH

CONSENT/AUTHORIZATION FOR PARTICIPATION IN A RESEARCH STUDY

Site Principal Investigator: **Raj C. Shah, MD**
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Protocol Title: **Does an Audio Wearable lead to Agitation Reduction in Dementia: The Memesto AWARD Proof-of-Principle Clinical Research Study**

Sponsor(s): **Edgewater Safety Systems, LLC and the National Institute on Aging (NIA)**

Name of Participant: _____

Note: *If you are the legal representative of a person unable to consent for him/herself, the terms "you" or "your" refer to the participant.*

INTRODUCTION: We are asking you to be in a research study. Research studies are voluntary. You do not have to participate. If you participate, you can stop at any time for any reason. Read this form and ask questions before deciding if you want to be in this research study.

PURPOSE: This study will test if a device (called Memesto) can reduce agitation in persons with Alzheimer's disease and related dementias (ADRD). Memesto is a wearable audio player being developed by Edgewater Safety Systems (Sponsor) that can be programmed to play music and/or personalized pre-recorded voice messages to calm the wearer.

Approximately 20 persons with ADRD currently living in a residential care facility will take part in this study. To take part, you must have **two** study partners – one family member and one professional caregiver from the facility - willing to provide information about you throughout the study.

PROCEDURES: Participation will last up to 12 weeks and involve 7 study

visits occurring every two weeks (either in-person or by telephone). At the first visit after you agree to participate by signing this form, personal and recent health information (including medication use) will be collected. You and your study partners will be trained on how to use Memesto and you will be given one to use until your next visit.

At the next visit (Baseline), you and/or your study partners will be asked questions about your mood, behavior, medications, and Memesto use. If you remain eligible to participate, you will be enrolled in the study and instructed to continue using Memesto for the next 10 weeks.

At all remaining visits (Weeks 2, 4, 6, 8, and 10), you and/or your study partners will be asked questions about your mood, behavior, medications, and Memesto use. You will return Memesto at the last visit (Week 10).

RISKS & BENEFITS: Wearing Memesto, music/voice messages played by Memesto, and repeated questions about your mood and behavior may be upsetting, frustrating, and/or tiring. There is a small risk of loss of confidentiality if your information is obtained by someone other than the study team, but precautions will be taken to prevent this.

You may not directly benefit from participation, but we hope that knowledge gained from this study may benefit others with ADRD in the future.

OPTIONS: You can choose not to participate. You do not have to be in this study to receive treatment for your condition.

COSTS & PAYMENTS: All costs will be paid for by the Sponsors. We will not pay you to participate.

Your participation may contribute to the development of commercial products from which the Sponsors or others may derive financial benefit. There are no plans to pay you for any of these developments.

PARTICIPATION: If you choose not to take part or stop participating early, your health care, benefits, and relationship with Rush University Medical Center will not be affected. If participation ends early, you may be asked to complete study activities that would have been done at the last study visit. Researchers and Sponsors also have the right to stop your participation without your consent if

they believe it is in your best interest, you do not follow study instructions, or the study is cancelled.

During the study, you will be told about new information or changes to existing information that may change your willingness to continue. If new information is shared, you may be asked to sign a revised consent form to continue participating.

Information collected may be used for future research or shared with other researchers. If this happens, information which could identify you will be removed before it is shared. Since identifying information will be removed, you will not be asked for additional consent.

CONFIDENTIALITY: This authorization is voluntary. Rush University Medical Center and its affiliates ("Rush") will not withhold or refuse your treatment, payment, enrollment, or eligibility for benefits if you do not sign this authorization. You do not have to sign this authorization, but that means that you cannot be in the study or receive study-related treatment.

By signing this document, you voluntarily authorize (give permission to) Dr. Raj C. Shah, his study team, and other Rush personnel involved with the conduct and review of this study (which may include off-site personnel) to use or disclose (release) health information that identifies you for the study described in this document.

During the study, Dr. Shah and his study team will collect Protected Health Information (PHI) about you for the purposes of this research. PHI is your health information that includes your medical history and new information obtained as a result of this study. Some of this information will come from your medical record. The health information that Rush may use or disclose for this research includes:

- Your name, address, phone number(s), date of birth, race/ethnicity, sex, study identification number, and recent health information as well as health information generated as part of this study.

Dr. Shah and his study team may share your health information and the results of your study-related procedures and tests with people outside of Rush who assist

with the conduct and review of this study. The persons who receive your health information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, but only if permitted by the laws governing them. Your health information described above may be used or disclosed to:

- The Researchers;
- The study Sponsors, Edgewater Safety Systems, LLC and the National Institute on Aging (NIA), and their representatives; and,
- Monitoring agencies such as the National Institutes of Health (NIH) and the Rush Institutional Review Board (IRB).

While you participate in the study you will have access to your medical record, but Dr. Shah is not required to release to you study information that is not part of your medical record. Rush is required by law to protect your health information, and study records that identify you will be kept confidential. The results of study tests/procedures performed as part of this study may become part of your medical record. Any study information in your medical record will be kept indefinitely. Your identity will not be revealed on any report, publication, or at scientific meetings.

You have a right to inspect and copy the information to be disclosed with this authorization and you may obtain a copy of the information by contacting the office listed below.

If you no longer want to be in the study and do not want your future health information to be used, you may change your mind and revoke (take back) this authorization at any time by writing to Dr. Raj C. Shah at 1750 West Harrison Street, Suite 1000, Chicago, IL 60612. If the authorization is revoked, you will no longer be allowed to participate in the study and previously authorized individuals/entities may still use or disclose health information that they have already obtained about you as necessary to maintain the integrity or reliability of the current study.

This authorization is valid for the entirety of this research study. It will expire upon completion of the study or if you revoke (take back) the authorization.

If you withdraw from this study, the data already collected from you may not be removed from the study records. The study doctor and/or study team may ask you whether they can continue to collect follow-up data on you. If follow-up information will be requested, you will be asked to sign a separate consent form before this information can be collected.

Records of participation in this study will be maintained and kept confidential as required by law. All of your information will be labeled with a special code and not with any identifying information.

The Rush Institutional Review Board (IRB) will have access to your files as they pertain to this research study. The IRB is a special committee that reviews new and ongoing human research studies to check that the rules and regulations are followed regarding the protection of the rights and welfare of human participants.

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. This research study can be found by searching for the following Clinical Trial Registry Number (NCT#): 5153161.

Certificate of Confidentiality: To help us protect you and the information we will be collecting from you, this study has obtained a Certificate of Confidentiality by the U.S. government. This Certificate means that researchers cannot be forced, even by courts or the police, to disclose any information about you.

The Certificate does not stop you from disclosing, or agreeing in writing to allow researchers to disclose, information about you. For example, if you would like an employer or insurer to know something about you that is documented in this study, you can write and sign a statement telling the researchers it is okay to give your employer or insurance company information.

For the protection of your privacy, this research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). The researchers may not disclose or use any information, documents, or specimens that could

identify you in any civil, criminal, administrative, legislative, or other legal proceeding, unless you consent to it. Information, documents, or specimens protected by this Certificate may be disclosed to someone who is not connected with the research:

(1) If there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases);
(2) If you consent to the disclosure, including for your medical treatment;
(3) If it is used for other scientific research in a way that is allowed by the federal regulations that protect research participants; and,
(4) For the purpose of auditing or program evaluation by the government or funding agency.

A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. Please contact the investigator for more information on how to provide this consent.

If you disclose actual or suspected abuse, neglect, or exploitation of an elderly adult, the researcher or any member of the study team must, and will, report this to Adult Protective Services, and/or the nearest law enforcement agency.

RESEARCH INJURY: If you get ill or injured from being in the study, Rush University Medical Center will help you get medical treatment. You should let the study doctor know right away that you are ill or injured. If you believe you have become ill or injured from this study, you should contact Dr. Shah at 1-312-563-2902.

You should let any health care provider who treats you know that you are in this study. If you do seek medical treatment, please take a copy of this document with you because it may help the doctors where you seek treatment to treat you. It will also provide the doctors where you seek treatment with information they may need if they want to contact your study doctor.

You or your health insurance plan will be billed. No money has been set aside to pay the costs of this treatment. Health insurance plans may or may not cover costs of research-related injury or illness. You should check with your insurance

company before deciding to participate in this research study. Costs not covered by insurance could be substantial.

Rush University Medical Center has no program for financial compensation or other forms of compensation for injuries which you may incur as a result of participation in this study. By signing this form, you are not giving up any legal rights to seek compensation of injury.

QUESTIONS: Questions are encouraged. Contact Dr. Shah at 1-312-563-2902 or Raj_C_Shah@rush.edu with questions about this study. Questions about the rights of research participants may be addressed to the Rush University Medical Center Office of Research Affairs at 1-800-876-0772.

PARTICIPANT OR PARTICIPANT'S LEGAL REPRESENTATIVE: By signing below, you are consenting to participate in this research study. You have read the information given or someone has read it to you. You have had the opportunity to ask questions, which have been answered satisfactorily to you by the study team. You do not waive any of your legal rights by signing this consent/authorization form. You will be given a signed copy of this form.

Participant Name	Participant Signature	Signature Date

Legal Representative's Name

Legal Representative's Signature	Signature Date

INDIVIDUAL OBTAINING CONSENT: I attest that 1) all the elements of informed consent described in this consent document have been discussed fully in non-technical terms with the participant/participant's legal representative, 2) all questions asked were answered to the best of my knowledge, and 3) the person signing is the participant/participant's legal representative and has done so voluntarily.

Individual Obtaining Consent's Signature	Signature Date