VUMC Institutional Review Board
Informed Consent Document for Research

Study Title:	Prevalence and Detection of Voice and Swallowing Disorders in Adults with and without Alzheimer's Disease
Version Date:	5/17/24
PI:	Cara Donohue, Ph.D. CCC-SLP

Name of participant: _____ Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

Key Information:
The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Key information about this study:
This research study is investigating cough, voice, and swallow function in healthy adults and individuals with Alzheimer's Disease (AD) between the ages of 60-100. Previous studies suggest that voice and swallow function change with aging, but the exact timing of when these changes occur, how they progress, and whether these changes lead to problems with voice and swallowing remains unknown. Additionally, swallowing and voice problems are known to occur in individuals with AD, but the exact prevalence, the timing of when these changes occur, how they progress, and risk factors for developing these problems is unknown. This study will involve one in-person research evaluation to our lab that will last approximately 1-1.5 hours and will consist of a screening, cough testing, swallow function testing, voice function testing, assessments of grip and tongue strength, and completion of questionnaires. Individuals who participate in this study will also be asked to complete the same questionnaires online one year and two years after their research visit. A potential benefit of participating in this research study includes receiving information about your cough, voice, and swallow function. This study also has the potential to lead to better screening tools and treatments for older healthy adults and individuals with AD at risk of developing dysphonia (voice problems) or dysphagia (swallowing problems). Risks of participating in this study include dizziness/lightheadedness, fatigue, muscle soreness, boredom, fainting, spasm of your vocal cords, nosebleed, gagging, vomiting, food/liquids entering the lungs, and loss of confidentiality.

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

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You are being asked to take part in this research study because you are either a healthy community dwelling adult between 60-100 years old or an individual with AD between 60-100 years old. You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study.

Side effects and risks that you can expect if you take part in this study:
This research study will involve cough testing, swallow function testing, voice function testing, grip strength and tongue strength testing, and completion of questionnaires. Possible side effects and risks of study procedures and treatments include:

- Dizziness/lightheadedness
- Fatigue
- Muscle soreness
- Boredom
- Discomfort of wearing nose clips
- Fainting
- Spasm of your vocal cords
- Nosebleed
- Gagging
- Vomiting
- Food/liquids going into the lungs
- Anxiety

Good effects that might result from this study:
The benefits to science and humankind that might result from this study:
This research study will provide data about cough, voice, and swallow function in healthy adults and individuals with AD between the ages of 60-100 years old. It has the potential to provide insight into the prevalence, progression, and risk factors for voice and swallowing impairments in elderly adults and individuals with AD to assist in developing accurate screening tools and effective, preventative interventions.

Procedures to be followed:
This study will consist of one research visit to our lab that will involve cough testing, swallow function testing, voice function testing, grip strength and tongue strength testing, and the completion of some

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questionnaires which will take approximately 1-1.5 hours. The swallow function test will involve the insertion of a small camera through the nose and into the throat area, and voice function testing will involve the insertion of a camera into your mouth to view your vocal cords over the back of your tongue. Individuals who participate in this study will also be asked to complete the same questionnaires online one year and two years after their in-person research visit.

Payments for your time spent taking part in this study or expenses:
You will be compensated with a $50 U.S. Bank debit card after completion of your in-person research evaluation.

You are not allowed to accept any money for taking part in this study if you are not eligible to receive money from a U.S. person or company or the U.S. government because of U.S. national security and/or foreign policy laws. You can still take part in the study however, you will not be paid if you are a resident of a country restricted by the U.S. government's comprehensive territorial sanctions or if you are listed on the U.S. Treasury Department's Office of Foreign Assets Control's Specially Designated Nationals (SDN) list of prohibited individuals. You do not have to say why you choose not to be paid.

Costs to you if you take part in this study:

There is no cost to you for taking part in this study.

Payment in case you are injured because of this research study:
If it is determined by Vanderbilt and the Investigator that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided **at Vanderbilt** to treat the injury.
There are no plans for Vanderbilt to pay for any injury caused by the usual care you would normally receive for treating your illness or the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

Who to call for any questions or in case you are injured:
If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact Cara Donohue, Ph.D. CCC-SLP at 615-932-4709, or email Emily Kimball, Ph.D. CCC-SLP at voice.lab@vumc.org.

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the VUMC Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

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Reasons why the research investigator may take you out of this study:
Individuals may be withdrawn from the research study by the Principal Investigator if they experience adverse side effects that are believed to be associated with the procedures being used in this study.

Additionally, all endoscopic videos from the swallowing and voice evaluation components of your research visit will be reviewed by a board-certified Otolaryngologist on our team for incidental findings. If any concerning findings are identified, you will be notified of recommended next steps via phone/e-mail.

If the Principal Investigator determines withdrawal from the study is necessary, they will contact you via phone/e-mail.

What will happen if you decide to stop being in this study?
If you decide to stop being part of the study, you should tell the Principal Investigator (Cara Donohue, Ph.D., CCC-SLP). Deciding not to be part of the study will not change your regular medical care in any way.

Clinical Trials Registry:
A description of this clinical trial will be available on www.clinicaltrials.gov (NCT06328374), 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.

Confidentiality:
Data collection will occur in a private room with the Principal Investigator or a trained research assistant. You will be assigned an alphanumeric code to protect your data from being identified. All your data will be stored in a locked file cabinet, a secure lab server, or entered/stored in REDCap, a secure web-based applications offered through Vanderbilt. Only approved research study personnel with HIPAA training and responsible conduct in research training will have access to your data.

This study may have support from the National Institutes of Health. If so, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means. It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help. Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

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Privacy:
Any samples and information about you may be made available to others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit as a result of the tests done on your samples. These tests may help us or other researchers learn more about the causes, risks, treatments, or how to prevent this and other health problems.

Study Results:
Research participants may indicate to the Principal Investigator if they are interested in results of this research study. This information will be tracked and deidentified data in the form of presentations and/or manuscripts will be shared with interested research participants once the study is complete.

Authorization to Use/Disclose Protected Health Information
What information is being collected, used, or shared?
To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Vanderbilt University Medical Center and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?
The people who may request, receive or use your private health information include the researchers and their staff. Additionally, we may share your information with other people at Vanderbilt, for example if needed for your clinical care or study oversight. By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you may not join the study.

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How long will your information be used or shared?
Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?
You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provide d in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

_____ _____
Date Signature of patient/volunteer

Consent obtained by:

_____ _____
Date Signature

_____
Printed Name and Title

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Surrogate Consent Rider for Research

☐ **Not applicable** – This participant did not enroll utilizing a healthcare decision maker and the surrogate consent rider.

I, _____ [name of decision-maker/surrogate], am the _____ [state relationship to participant] of _____ [state participant's name]. I have read the informed consent document or it has been explained to me. I have had the opportunity to ask any questions and all of my questions have been answered. I have been informed that an investigational treatment may be administered to _____ [participant's name]. I believe receiving such treatment would be in the interests of _____ [participant's name] and is consistent with what he/she would have decided had he/she been able to do so.

Your decision to allow your family member/friend to participate in this research study is voluntary. You may choose not to allow his/her participation and he/she will receive alternative treatments without affecting his/her healthcare/services or other rights. You are also free to withdraw him/her from this study at any time. In the event new information becomes available that may affect the risks or benefits associated with this research study or your willingness to allow continued participation in this research study, you will be notified so that you can make an informed decision whether or not to continue your family member/friend's participation in this study.

Your family member/friend will periodically be re-evaluated for the capacity to give consent. If he/she is found to be capable, continued participation in this study would only occur with his/her consent.

_____ ___/___/___

Signature of Health Care Decision-Maker/Surrogate Date

_____ ___/___/___

Signature of Witness Date

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_____ ___/___/___

Name and Signature of person obtaining consent Date