

Title of Research Study: Detecting Mild Cognitive Impairment and Probable Alzheimer's Disease from Speech using Linguistic Deficits with Amyloid PET Imaging as a Baseline.

Principal Investigator: Sylvester Olubolu ORIMAYE, PhD

Principal Investigator's Contact Information: orimaye@etsu.edu or 423-676-9667

Organization of Principal Investigator: East Tennessee State University

INFORMED CONSENT

This Informed Consent will explain about being a participant in a research study. It is important that you read this material carefully and then decide if you wish to voluntarily participate.

A. Purpose: The purpose(s) of this research study

The purpose of this study is to find a new and cheaper method to detect Alzheimer's disease at an earlier stage. It is possible to do early detection by understanding basic changes from your speech. We hope that the result of the simple technique will be as good as your previous brain scan. All you need to do is to describe a picture and we will record your voice during that time.

B. Duration:

Each participant will volunteer one visit to the ETSU Innovation Lab within the business hours. Each visit may take between 10 to 15 minutes. The number of participants is 20.

C. Procedures: The procedures, which as a participant in this research will involve you, include

As a participant in this study, your previous PET scan results and MMSE with the Psychiatry research division of the ETSU Innovation Lab will be accessed for data analysis.

You will be asked to undergo another MMSE.

You will be asked to describe the scenes on a projected picture, while your voice will be recorded with an audio recorder. The description is expected to take between 10 to 15 minutes on average. Nevertheless, you will be given as much time as you need to describe everything you can see in the picture.

D. Alternative Procedures/Treatments: There is no alternative procedure available to you if you elect not to participate in this research study.

E. Possible Risks/Discomforts:

There is minimal risk from your participation in this research study.

There is a possibility that you may be anxious to know what your participation may likely reveal about you. At the same time, please note that your participation is NOT a test of intelligence or function of your brain. It is meant to understand the pattern of speech from a group of participants like you. Therefore, there will be no individual outcome for you from this study.

There is also the risk of loss of confidentiality while your PET scan result is accessed by a study staff.

You must meet the following criteria to be included in the study:

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1. You will be asked to undergo the Mini-Mental State Examination (MMSE) and you agree to release the score for this study.
2. You have undergone Amyloid PET scan with a diagnosis of having the Amyloid plaques or not and you agree to release the diagnosis for this study.
3. You have moderate to fluent English language speaking ability.
4. You are an adult, age 18 or over.

You will be excluded from this study if you are:

1. a participant who cannot speak as the data collection process needs to record your voice.
2. a participant who is severely demented or at a very late stage of Alzheimer's disease.
3. a participant with stroke.
4. a participant with a history of other brain disorders than Mild Cognitive Impairment and Alzheimer's disease.
5. a participant with serious vision impairment or who cannot see with the aid of corrective glasses.
6. a participant who cannot speak in the English language.
7. a participant who self-report that s/he have been diagnosed with HIV/AIDS as this may have effects on its own.

Below are the conditions under which you may be removed from the research by the investigator without your consent:

1. If you need a medical emergency.
2. If you become violent during the data collection.
3. If you do not respond to the staff member who will be recording your voice and shows no further interest in communicating further.

F. Possible Benefits:

Please note that there are no potential benefits for you as an individual participant. Nevertheless, this study could potentially give the following benefits to the research on and diagnosis of Mild Cognitive Impairment and probable Alzheimer's disease:

1. Provides a less expensive diagnosis for detecting Mild Cognitive Impairment and probable Alzheimer's disease for early intervention.
2. A less invasive diagnosis Mild Cognitive Impairment and probable Alzheimer's disease.
3. An opportunity for screening of Mild Cognitive Impairment and probable Alzheimer's disease among the remote population.
4. Opportunity for accessible health services to the aging population in remote communities.

G. Compensation in the Form of Payments to Participant:

Participation in this study is voluntary. There is no compensation in the form of payment or gift to the participants.

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- H. Voluntary Participation:** Your participation in this research experiment is voluntary. **You may choose not to participate.** If you decide to participate in this research study, you can change your mind and quit at any time. If you choose not to participate, or change your mind and quit, the benefits or treatment to which you are otherwise entitled will not be affected. You may quit by calling Dr. Sylvester Olubolu ORIMAYE, at 423-676-9667. You will be told immediately if any of the results of the study should reasonably be expected to make you change your mind about continuing to participate.
- I. Contact for Questions:** If you have any questions, problems, or research-related medical problems at any time, you may call Dr. Sylvester Olubolu ORIMAYE, at 423-676-9667, or Dr. Karl GOODKIN, at 423-439-2233. You may also call the Chairperson of the ETSU Institutional Review Board at 423.439.6054 for any questions you may have about your rights as a research participant. If you have any questions or concerns about the research and want to talk to someone independent of the research team or you can't reach the study staff, you may call an IRB Coordinator at 423.439.6055 or 423.439.6002.
- J. Confidentiality:** Every attempt will be made to see that your study results are kept confidential. A copy of the records from this study will be stored in a secured locker at the ETSU Innovation Lab for at least 6 years after the end of this research. The results of this study may be published and/or presented at meetings without naming you as a participant. A description of this study will be available on: <https://clinicaltrials.gov/> and www.alz.org/TrialMatch as required by law. This website will not include information that can identify you. At most, the website will include a summary of the results of the study. You can search this website at any time. Although your rights and privacy will be maintained, the Secretary of the Department of Health and Human Services, ETSU IRB, and Dr. Sylvester Olubolu ORIMAYE and his research team have access to the study records. Your (medical) records will be kept completely confidential according to current legal requirements. They will not be revealed unless required by law, or as described in this form.
- K. Financial Cost:** Please note that there could be a cost of travel to the study site (ETSU Innovation Lab). You will not be reimbursed for the cost of travel. Your participation in the study is voluntary.

HIPAA Authorization

Authorization for Disclosure of Protected Health Information for Research

- A. Purpose:** The purpose of this authorization form is to authorize Dr. Sylvester Olubolu Orimaye and his research team to collect, use, and disclose your protected health information to conduct the research study listed above. This authorization will inform you what information about you may be collected in this study as well as who might see or use your information. East Tennessee State University has rules that require the research team to protect your health information. There are also federal and state laws that protect the privacy of your health information. Generally, only people on the research team will know that you are in the research study and will see your protected health information. However, there are a few exceptions that are listed in Section C of this form.

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By signing this authorization form, you authorize the research team to collect, use, and disclose your health information as described in this form. **You do not have to sign this form.** Your decision not to sign this authorization will not affect your treatment, healthcare, enrollment in health plans, or eligibility for benefits. However, your decision not to sign this form will result in your not being allowed to participate in this research study.

B. Protected Health Information to be Used/Disclosed: Protected health information is the information in your medical or other healthcare records. This includes all information in your records that can identify you including your name, address, phone number, birth date, and account numbers.

1. By signing this form you authorize the following healthcare providers, health plans, or other organizations or individuals to disclose your protected health information to the research team:
 - ETSU Psychiatry Research Division

2. By signing this form you authorize the individuals or organizations listed above to disclose the following types of protected health information to the research team:
 - Diagnostic imaging reports
 - MMSE test score
 - Name
 - Phone Number
 - Email
 - Postal Address
 - Date of Birth or Age

3. By signing this form you authorize the research team to collect, use and disclose your protected health information as listed above during the following time period: July 2019 – August 2020.

C. How your protected health information will be used: Dr. Sylvester Olubolu Orimaye and his research team will collect, use and disclose the protected health information described in this form for the purpose of conducting the research study listed on this form. Generally, only Dr. Sylvester Olubolu Orimaye and those individuals on the research team will see your protected health information. However, in certain circumstances the following individuals or organizations may have access to your protected health information:

1. The Department of Health and Human Services
2. The ETSU Institutional Review Board
3. The ETSU Human Research Protection Program
4. The ETSU HIPAA Compliance Office
5. Other representatives of ETSU as reasonably required to carry out the research study
6. The United States Food and Drug Administration
7. Other Individuals/Organizations as required by law

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- D. Rediscovery of your protected health information:** Once your protected health information is disclosed to anyone outside this research study, the information may no longer be protected by the federal privacy standards and may be redisclosed without obtaining your authorization. Dr. Sylvester Olubolu Orimaye and his research team will only collect, use and disclose your protected health information as described in this form or as otherwise permitted or required by law.
- E. Right to revoke this authorization:** If you sign this authorization form, you may change your mind at any time. If you change your mind, the research team may still keep and use your protected health information that they already have. The research team will not obtain any more protected health information about you for this research unless permitted or required by law after you change your mind.

In order to change your mind and revoke this authorization, you must send a written letter to:

**Susan Wallace
Dept. of Psychiatry & Behavioral Science
Quillen College of Medicine
Box 70567
Johnson City, TN 37614**

If you change your mind you will no longer be able to participate in this research study.

- F. Expiration of authorization:** This authorization will expire at the end of this study.
- G. Questions about Privacy:** If you have any questions or concerns about your privacy rights you may contact the East Tennessee State University HIPAA Compliance Office via telephone 423.439.8533 or mail P.O. Box 70285, Johnson City, TN 37614.

By signing below, I confirm that I have read and understand both the Informed Consent and HIPAA Authorization sections of this form and that I had the opportunity to have them explained to me verbally. You will be given a signed copy of this informed consent document. I confirm that I have had the opportunity to ask questions and that all my questions have been answered. By signing below, I confirm that I freely and voluntarily choose to take part in this research study, and that I authorize Dr. Sylvester Olubolu Orimaye and his research team to collect, use and disclose my protected health information as described in this form.

By signing below, I confirm that I have read and understand this Informed Consent Document and that I had the opportunity to have them explained to me verbally. You will be given a signed copy of this informed consent document. I confirm that I have had the opportunity to ask questions and that all my

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Signature of Participant Date

Printed Name of Participant Date

If signed by someone other than the Participant, state your relationship to the Participant and a description of your authority to act on the Participant's behalf:

Signature of Principal Investigator Date

Signature of Witness Date