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| <b>Study Title</b>          | Early-Onset Alzheimer's Disease Phenotypes:<br>Neuropsychology and Neural Networks. |
| <b>NCT Number</b>           | NCT03153371   |
| <b>Document Description</b> | Informed Consent Form (Healthy Control)   |
| <b>Document Date</b>        | 19 December 2019  |

University of California, Los Angeles

## **CONSENT TO PARTICIPATE IN RESEARCH**

*Early-Onset Alzheimer's Disease Phenotypes: Neuropsychology and Neural Networks*

Mario F. Mendez, MD, PhD, from the Department of Neurology at the University of California, Los Angeles (UCLA) is conducting a research study.

You were selected as a possible participant in this study because you are a normal control. Your participation in this research study is voluntary.

### **Why is this study being done?**

This study is being done to better understand variations within Alzheimer's disease, especially focusing on syndromes that do not mostly impact memory (including frontotemporal dementias).

### **What will happen if I take part in this research study?**

If you volunteer to participate in this study, the researcher will ask you to do the following:

- Sign permission for certain information from your medical record to be reviewed used for this research study.
- Answer about 1 hour of questions about your health background and history.
- Have a 45-minute-long magnetic resonance imaging (MRI) scan of your brain.
- Complete between 6 and 9 hours of neurological tasks and paper-and-pencil type cognitive testing (split into three sessions).
- Testing will take place at UCLA Medical Plaza 300.

### **How long will I be in the research study?**

Participation will take a total of about one year. There will be four visits when you first enroll, and then three more visits approximately one year later. The Year 1 visits will be about 3 to 4 hours long, for a total of approximately 9 to 12 hours. The Year 2 visits will be about 3 hours long, for a total of approximately 9 hours.

### **Are there any potential risks or discomforts that I can expect from this study?**

The risks of this study are risks to confidentiality, risk of claustrophobia, and risk of distress related to testing.

- **Confidentiality:** Information about you is protected by a federal Certificate of Confidentiality. This means that we can't be forced to release information about you for any legal proceeding, even if a court of law asks.

The Certificate allows us to use information about you for purposes of this research or to disclose it for other research when allowed by law. The Certificate requires other researchers to also protect information we share with them.

There are limits to this protection. The Certificate does not protect your information when:

- You or your family voluntarily release information about yourselves.
  - You consent to release of information (for example, the uses described in this form, or if you sign release forms for employment, insurance or medical care).
  - A federal agency audits or evaluates research that it funds.
  - Researchers are required to report possible intent to harm yourself or others, child abuse, elder abuse, or infectious disease cases.
- Claustrophobia and noise: Some people become anxious and upset due to the enclosed space or loud noises of the MRI machine. There will be an intercom for you to talk to the technician, and you can ask to stop at any time.
  - Distress related to testing: Completing the neurological tasks and cognitive tests involved in this study might cause you to become self-conscious of things that are difficult for you. This may lead you to feel sad, anxious or depressed. The tester will remind you simply to try your best, and you can ask for breaks or to stop if you need.

### **Are there any potential benefits if I participate?**

You will not directly benefit from your participation in the study.

The results of the research may help clinicians diagnose unusual types of Alzheimer's disease and help in the development of clinical trials for new treatments.

### **Will I be paid for participating?**

- You will receive a small stipend of \$25 per visit in the form of a gift card for your participation in the study. You will also receive a parking voucher to if needed to cover the cost of parking.
- *The study will pay for the cost of the MRI and any other study items and services as described in this consent form.*

### **Will information about me and my participation be kept confidential?**

Any information that is obtained in connection with this study and that can identify you will remain confidential. It will be disclosed only with your permission or as required by law. Confidentiality will be maintained by de-identifying the data with participant code. Identifiers will be stored in secured word protected computers and in locked cabinets.

### **What are my rights if I take part in this study?**

- You can choose whether or not you want to be in this study, and you may withdraw your consent and discontinue participation at any time.
- Whatever decision you make, there will be no penalty to you, and no loss of benefits to which you were otherwise entitled.
- You may refuse to answer any questions that you do not want to answer and still remain in the study.

## Who can I contact if I have questions about this study?

- **The research team:**  
If you have any questions, comments or concerns about the research, you can talk to the one of the researchers. Please contact Dr. Mario Mendez at 310-478-3711 X42696 or via e-mail at MFmendez@mednet.ucla.edu.
- **UCLA Office of the Human Research Protection Program (OHRPP):**  
If you have questions about your rights while taking part in this study, or you have concerns or suggestions and you want to talk to someone other than the researchers about the study, please call the OHRPP at (310) 825-7122 or write to:

UCLA Office of the Human Research Protection Program  
11000 Kinross Avenue, Suite 211, Box 951694  
Los Angeles, CA 90095-1694

***You will be given a copy of this information to keep for your records.***

## FUTURE RESEARCH OPPORTUNITIES

From time to time, new research studies may arise for which you are eligible. Please check the appropriate box and initial:

- \_\_\_\_\_ **I agree to be contacted in the future regarding possible participation in future research studies.**
- \_\_\_\_\_ **I DO NOT agree to be contacted in the future regarding possible participation in future research studies.**

Taking part in this study is your choice. You can choose whether or not you want to participate. Whatever decision you make, there will be no penalty to you and you will not lose any of your regular benefits.

- You have a right to have all of your questions answered before deciding whether to take part.
- Your decision will not affect the medical care you receive from UCLA.
- If you decide to take part, you can leave the study at any time.
- If you decide not to take part, you can still receive medical care from UCLA.

If you agree to participate in this study you should sign and date below. You have been given a copy of this consent form and the Research Participant's Bill of Rights to keep. You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

**SIGNATURE OF STUDY PARTICIPANT**

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Name of Participant

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Signature of Participant

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Date

**SIGNATURE OF PERSON OBTAINING CONSENT**

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Name of Person Obtaining Consent

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Contact Number

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Signature of Person Obtaining Consent

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Date