

## What to Expect on Your Screening Visit

### About The ADvance Study

The ADvance Study is researching the use of deep brain stimulation of the fornix (known as DBS-f), a place in the brain that plays a central role in memory, in people with Alzheimer's disease. DBS-f uses a surgically implanted medical device, similar to a heart pacemaker, to deliver mild electrical pulses to precisely targeted areas of the brain. The ADvance Study will initially involve about 20 people between the ages of 45 and 80 that have been diagnosed with mild Alzheimer's disease.

FOR MORE INFORMATION,  
VISIT:

[www.ADvanceStudy4AD.com](http://www.ADvanceStudy4AD.com)

All subjects in the study will have a DBS-f system implanted, with the stimulation device turned on for half of the subjects, and off for half. If your device is left off at the start of the study, you will have it turned on after 12 months. Your physical health, psychological state and level of physical skills, memory and thinking patterns will be tested before and for 18 months following implantation of the system. The DBS-f system or certain components of the system are likely to remain in your body for the rest of your life.

### Who Can Participate in This Study?

You may be eligible for the ADvance study if you meet several factors, including:

- Are 45-80 years old
- Have been diagnosed with mild Alzheimer's
- Have a reliable informant (spouse, relative, caregiver) who can attend all study visits and report on your daily activities and function
- Live at home and are likely to remain at home for the study duration
- Are in good general health
- Are on a stable dose for at least two months of an FDA approved drug for Alzheimer's — Aricept (donepezil), Razadyne (galantamine), or Exelon (rivastigmine)

### What Is the Screening Visit?

Potential candidates for the ADvance Study will participate in an initial screening visit to determine if you are appropriate for the study. During this appointment, you will come with your primary caregiver and complete a series of tests to help the physician understand your current level of physical skills, memory and thinking patterns. You will also have a physical exam and have your blood drawn. You will be reimbursed for your travel expenses associated with the screening visit.

### What Is Informed Consent?

Before you undergo any tests or interviews during the screening visit, you will be informed about the study purpose, what will happen during the visit, the risks of any procedures you will undergo, your rights as a study subject and privacy of your personal information and other issues. Then you will be asked to read and sign an Informed Consent Form, a legally required document

that confirms you have been informed about the study. Staff from the treatment clinic will walk you through the form and answer any questions you may have. Your primary caregiver will need to sign the Informed Consent as well.

### **What Will Happen to Me During the Screening Visit?**

The screening visit will involve a physical examination as well as psychological and memory testing.

The physical exam will include:

- Discussion with your doctor about your general health, past history and your medications
- Blood draw to get your baseline levels
- Electrocardiogram (EKG or ECG) to check the electrical activity of your heart

You will meet with a psychiatrist to discuss your psychological medical history. You will also complete a series of questionnaires/interviews during this visit. Your primary caregiver will need to participate in some of these assessments. These tests will assess your memory and reasoning abilities, physical skills, psychological state, behavior and changes in function related to your memory.

### **How Long Will the Visit Last?**

Depending on the site and circumstances, the screening visit will take anywhere from 4 to 6 hours to complete. There will be space to relax with reading materials for the time between tests. If this is too long for you, then you may be able to come on two separate visits.

### **Should Someone Come With Me To the Screening Visit?**

Yes. You will need to bring the same family member or primary caregiver with you to this screening visit and all future appointments involved in the study. This person should be familiar with your daily activities and will participate in some of the interviews about your condition. He or she will also be required to co-sign your Informed Consent. Make sure that the person who comes with you is familiar with this study by reading this document and other materials that you have about the ADvance Study. Information can also be found at [www.ADvancestudy4AD.com](http://www.ADvancestudy4AD.com).

### **What Should I Bring to the Screening Visit?**

Come to the visit well rested and well fed so that you can perform to your full abilities in the tests. Bring a copy of your health records or a summary of your health issues and medical procedure history. Bring the bottles of all of the medications that you currently take or a list of your current medications and dosages. Also bring a pad for writing down your questions and taking notes

### **What Happens After My Screening Visit?**

Your doctor will review all your information after the visit. If your medical and test results meet the study criteria, you will be asked to return to the clinic to discuss participating in the research study.