

# A Road Map to Research Participation



Aging & Memory Loss

Road Map Series

I. Dementia Diagnosis

II. Research Participation

III. Caregiving

## Have you ever considered participating in clinical research?

Did you know the first person to be cured of Alzheimer’s disease will be in a clinical trial? Research participation is a great opportunity to contribute to research by either receiving new experimental treatments or being observed over time. Research participants help us work towards finding a cure for Alzheimer’s disease and related dementias. There are many ways Alzheimer’s research is conducted. The two most common types of studies are clinical trials and observational studies.

## What is a clinical trial?

**Clinical trials** are research studies used to test the safety and effectiveness of a new therapy. During clinical trials, participants are randomized into two or more groups and receive the new treatment or a placebo. Often described as a “sugar pill,” a placebo is used to observe the effects of the experimental medication compared to no treatment. During the study, both you and the study team will be blinded (not know) which group you are in. Your safety is monitored closely during the course of a study.

**Observational studies** are different from clinical trials because no treatment is involved. However, they are still extremely important for us to understand how brain diseases develop. During observational studies, scientists perform clinical evaluations, such as memory and thinking tests and physical exams, collect images and carry out medical tests, like blood draws and lumbar punctures to observe changes in your brain over time. These studies are a great option for those who would prefer fewer visits to the research center and/or are not interested in receiving experimental treatment.

## What is involved in a clinical trial?

The following pages will give you an idea of what it’s like to participate in clinical research and observational studies. Every study is different, but these are some of the most common components of participation.



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**MASSACHUSETTS**  
Alzheimer's Disease  
Research Center

**BRIGHAM HEALTH**



**BRIGHAM AND WOMEN'S**  
Center for Alzheimer Research and Treatment

## Step 1: Pre-Screening



If you're interested in participating in a clinical trial, the first step is a pre-screening phone call during which you may review your medical history and undergo a short memory test. The phone call will help us determine which study you may qualify for. Each study has different inclusion and exclusion criteria for enrollment. Some of the most common reasons for **exclusion** from a clinical trial are:

- Exclusionary medications, such as seizure medications, stimulants for ADHD, or the regular use of certain sedatives
- Scores either too high or low on memory tests
- Diagnosis and/or treatment of cancer within the past 2-5 years
- Other neurodegenerative diseases or head trauma

During this initial phone call, you may also be asked to sign a **Medical Record Release Form**. This form allows us to review your medical records to further determine if you are eligible for any of our studies. On this form, you will fill out your basic contact information and list any doctors that you see regularly, including your neurologist (if you have one). Our staff will then request your medical records, and have our study physicians review them.

When your medical record review is complete, we will call to let you know which studies you are eligible for. If you are eligible for multiple studies, we will give you more information to review about each study so you may choose between them. We will often give you the **consent form** for the study because the document reviews what happens in the study in greater detail, the risks involved, and your rights as a participant. You will not need to memorize or sign it at home. The consent form will be discussed in detail with you at your first visit. Our research staff and research ambassadors (previous and current research participants) will be available to answer all your questions and concerns.

In order to participate in a trial, you will need a **study partner**. Your study partner should be someone who knows you well and with whom you spend time on a regular basis. Some examples of a good study partner are a spouse or partner, a family member, or a close friend. Your study partner will be required to answer questions about your memory, daily functioning, or mood and behavior.

## Step 2: Screening Visit

The initial screening visit for a study is a 3-5 hour appointment that includes several components:

- Reviewing the **consent form** with one of our study physicians
- Taking your vitals and possibly obtaining a blood sample, urine sample, or an EKG
- Reviewing your medical history and current medications
- Cognitive testing and questionnaires about your daily activities, mood, and behavior



Screening evaluations are important to ensure a study is safe for you. You must pass each of these components in order to qualify for the trial. You may screen-fail (found to be ineligible for the study) at any point during the screening visit. Common reasons for screen-failing include:

- Scoring too high or too low on the memory tests
- Abnormal blood, urine, or EKG
- Answers to the questionnaires that exclude you on the basis of your dementia diagnosis

If you screen fail, we will look for additional studies for you. If you pass all of these components, you will then schedule appointments for additional appointments such as magnetic resonance imaging (MRI) and/or positron emission tomography (PET) scans. These are used to further determine eligibility based on pictures of your brain.

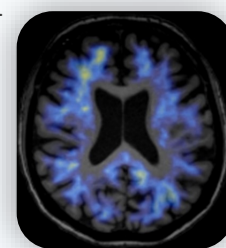
### Step 3: MRI and PET scans

As a part of the screening process, you will usually undergo an MRI and PET scan.

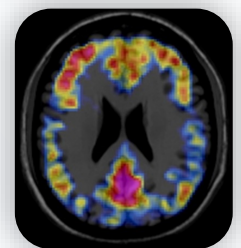
**MRI:** MRI stands for magnetic resonance imaging. These scans are used to monitor safety during trials, and signs of strokes, tumors, areas of bleeding, and volume changes in your brain.

**PET:** PET stands for positron emission tomography. These scans use radioactive contrast to measure levels of amyloid and tau proteins in the brain. Many investigational drugs target one of these two proteins, so the PET scans help researchers to monitor treatment response.

You may be excluded from the trial based on the results of your MRI or PET scan. In some trials, you need to have a certain level of amyloid protein build-up to qualify. In addition, if certain abnormalities are found on your MRI scan such as a tumor, you may be excluded.



Normal Brain  
Amyloid PET Scan



Alzheimer's Disease  
Brain Amyloid PET Scan

### Step 4: Lumbar Puncture (may be optional)

Some of our trials include a Lumbar Puncture, or *spinal tap*, to extract a small amount of cerebrospinal fluid (CSF) from the spinal column. The procedure is often an optional study component, however some trials may require it. This is done by using a local anesthetic on your lower back and inserting a small needle between two of your vertebrae. This fluid is then analyzed for the same amyloid and tau proteins visible through PET scans. Lumbar punctures are conducted by medical experts with extensive experience performing the procedure. For more information about lumbar punctures, ask our staff for study-specific handouts.



## Why do I need a study partner?

Study partners are required for many reasons. Most importantly, they are your advocate! Other reasons study partners are important are:

- They can assist in decision making and visit scheduling
- They help participants remain engaged
- They can assist in medication management if needed
- They will be asked to share observations regarding the participant's daily functioning, mood, behavior, and memory

## Step 5: Baseline/Randomization Visit

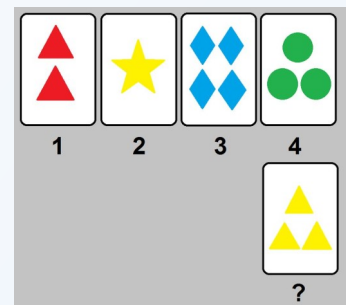
Once you have passed the previous 3-4 steps, you will attend your **randomization visit**, in which you will receive the first dose of either the medication or placebo. This visit may last up to four hours, which can include memory testing, questionnaires for both you and your study partner, vital sign collection, and blood and/or urine collection. You will then receive the dose, either via pill, infusion, or injection. You may be asked to stay at our center for a period of time after the first few doses for safety monitoring.

## Routine Study Visits

Following this initial visit, you will come in at regular intervals for *routine study visits*. These visits include infusion or drug-distribution visits. Some visits may include some additional memory testing or questionnaires for you and your study partner or brain scans.

## Memory Testing

Cognitive testing will occur during your first screening visit and your baseline visit, as well as periodically throughout the rest of the study. These tests are used to determine changes in certain aspects of cognition such as executive function and memory over the course



of the study. Most of the testing consists of tasks such as drawing shapes, remembering short lists of words, identifying names of objects, and remembering components of a short story. Some other tests may be completed using a tablet or computer. You will also fill out a variety of questionnaires either on your own or with one of our qualified raters. These questionnaires ask about changes in daily activities, memory, mood, behavior, and general health and wellbeing. These questions are also used to assess any changes over time and will be answered by both you and your study partner.

## Study Drug Administration

If you are on a study that includes an experimental medication, we will always ask you about your current medical conditions, medications, and any changes that may have occurred since your last study visit. Study drug administration is study-specific and the form in which the drug is administered will vary.



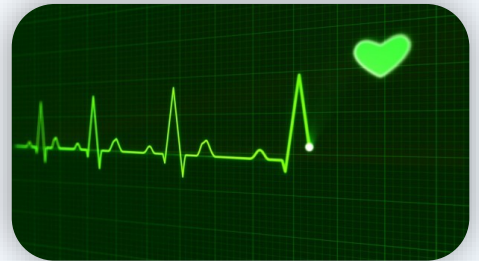
For some studies, the drug is in the form of a pill, and is taken orally each day over the course of the study. In other studies, the drug is given through an intravenous (IV) infusion. The duration and frequency of these infusions is dependent on the study. These visits involve having a study nurse place an IV, which will be used to give the infusion. Study drug is given using an IV pump under the supervision of study nurses, neurologists, and/or physician assistants. After the study drug has been administered, the IV is removed.



For other studies, the study drug is delivered through an injection into the tissue (usually shoulder or abdomen). These injections are given by a study nurse. The frequency of these injections is dependent on the study.

## Labs and EKG

At screening visits and throughout the duration of the study, intermittent safety labs and EKGs will be conducted. The primary reason is to confirm that you are relatively healthy and to monitor any clinically significant changes over time. In clinical trials, this also serves to ensure that you are not experiencing any adverse effects due to the experimental medication. The secondary reason is to evaluate the effectiveness of the medication and to store samples for future research, with your consent.



## Concerned about transportation to and from the center?

We proudly provide free transportation for all our research participants! We also reimburse participants with a visit stipend for each study visit. BWH is easily accessible via public transportation. Additionally, if you choose to drive, we validate parking for the 60 Fenwood garage. Some studies also provide a complimentary car service if you and your study partner are unable to drive or take public transportation.

**Please call our recruitment specialist for more information: (617) 525-9554**



## Where are we located?

### **BWH Center for Alzheimer Research and Treatment**

60 Fenwood Road, 1st Floor  
Boston, MA 02115  
(617) 732-8085

### **MGH Memory Disorders Unit**

15 Parkman St  
Boston, MA 02114  
(617) 726-1728

### **MGH Charlestown Navy Yard**

149 13th Street  
Charlestown, MA 02129  
(617) 726-3197



## Clinical Trial FAQ's

### **Do I have to pay or will my insurance be charged to participate?**

No, all study-related activities are free to you and are paid for by the pharmaceutical company, the NIH, foundations, philanthropic funds, or other research grants. If you opt to see one of our neurologists in clinic outside of the study, this will be charged to your insurance. However, all study visits, scans, medications, and expenses are free to you.

### **Are the drugs being tested FDA-approved?**

Not yet. If successful, the drugs in our trials will be submitted for FDA-approval following completion of a Phase III trial (the last stage of testing of a drug). However, the majority of our trials are in phases II or III, meaning that much of the safety testing has already been completed during phase I, and the focus is now on efficacy.

### **What happens when the study is over? Will I have a chance to take the drug at that point if I was on the placebo?**

Some of our trials have what is called an “open-label extension” phase, in which all participants take the drug, regardless of previous status in the placebo or drug group, in this extended part of the study. Not all trials have this extension phase, and some may not guarantee this phase until after an interim analysis is performed.

### **What information will I be getting about my health/cognitive function throughout the course of the study?**

During the course of the study, you will not receive individual scores and results of tests and scans, as this introduces the risk of bias to the study. However, if anything clinically significant (problematic or dangerous to your health) is found either during the testing or the scans, you will be notified and guided to receive the appropriate clinical care. In addition, you may ask to set up a meeting with one of our study physicians to discuss your test scores and how you are doing in the study.

### **What are the chances of receiving the drug vs. the placebo?**

This differs between studies. In some studies, the groups are split 50-50, and in some there are multiple treatment groups with different doses. In this case, your chance of receiving the drug may be, for example, 2 out of 3, or 3 out of 4.

## **Will you talk to my neurologist or my doctor before I enroll? Will my neurologist or doctor receive the results of my testing as the study progresses?**

We will contact your neurologist and primary care physician to obtain your medical records prior to screening. After enrollment, we will update your care team about your status in the study, as well as if there are any concerning findings on testing, scans, or labs.

## **What are the side effects of the study drug?**

This differs between studies. Study drugs may have minor side effects such as headaches, dizziness, or nausea or more significant side effects such as temporary and reversible swelling in the brain. All side effects will be outlined in the consent form, which must be reviewed thoroughly and signed before taking part in the study.

## **When will I receive the results of the study?**

When all participants have completed the study, in other words, when the final participant across all sites completes the double-blind portion of the trial, the sponsor will spend a few months checking for errors and analyzing the data, and then the preliminary results will be released to the public. You will then be notified of whether you had received drug or placebo.

## **Testimony from our Study Participants**

“The duration of the study is not a disadvantage but rather an advantage. I’d bet participants like myself never want connection to the staff & participants in the study to end. We joke that we never want to be retired from the study!”

“Stepping into the “environment” of the study is not depressing. Just the opposite - it is uplifting, restorative, and engaging. You are a part of something very important ... you sense that you are highly valued and forever appreciated. You are at the center of current research, information, and guiding direction - a good place to be!”

“Everyone that works here is so kind and friendly. It makes it so much less stressful”

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## Resources for Patient and Caregiver Support

### Alzheimer’s Association

The premier source of information for advocacy, research information, support programs, and education.

MA/NH Chapter contact: *617-868-6718*

24-hour national Helpline: *1-800-272-3900*

### The Association for Frontotemporal Degeneration

Research, awareness, support, education, and advocacy for people affected by Frontotemporal Degeneration and their caregivers.

Helpline: *1-866-507-7222*

### Lewy Body Dementia Association

Provides support through outreach, education, and research to those affected by Lewy body dementias.

Lewy Body Dementia Caregiver Number: *888-204-3054*

### National Institute on Aging: Alzheimer’s Disease Education and Referral Center (ADEAR)

The latest dementia related news and publications on diagnosis, treatment, care, and research.

Toll-free contact: *1-800-438-4380*

### Alzheimer’s Foundation of America

Provides direct services and educational resources to patients and caregivers.

National toll-free hotline: *866-232-8484*

## National Clinical Trial Information

You or a loved one’s participation in research studies will significantly help in the search for more effective treatments for Alzheimer’s Disease and related dementias. The following resources provide information regarding the range of national clinical trials:

### National Institute on Aging: Alzheimer’s Disease Education and Referral Center (ADEAR)

Toll-free contact: *1-800-438-4380*

### Alzheimer’s Association TrialMatch

24-hour Helpline *1-800-272-3900*

### Alzheimer Prevention Network

[alzpreventionnetwork.org](http://alzpreventionnetwork.org)

<b>MADRC Research Clinics</b>	
BWH Center for Alzheimer Research & Treatment	(617) 732-8085
Frontotemporal Disorders Unit	(617) 726-1728
Lewy Body Dementia Movement Disorder Unit	(617) 726-5532
Alzheimer’s Clinical & Translational Unit (ACTRU)	(617) 643-2351