JOHNS HOPKINS MEDICINE

Approved August 9, 2022

ALLFTD
ARTFL LEFFTDS Longitudinal Frontotemporal Lobar Degeneration

ALLFTD IS SEEKING ADDITIONAL FAMILY MEMBERS (BLOOD RELATIVES) OF ENROLLED MEMBERS TO PARTICIPATE IN THE STUDY.

The ALLFTD Study is a research study for Frontotemporal Lobar Degeneration funded by the National Institute of Neurological Disorders and Stroke in the National Institutes of Health. The knowledge gained from ALLFTD and similar studies are driving the development of therapies for this rare disease. ALLFTD is seeking additional blood relatives (family members) of enrolled study participants to join our study. One or more of your family members is already participating and is sharing this information with you to help you learn more about FTLD and the importance of participating in research. Many people participate because they want the research to benefit their children and others in the family.

***You can learn more about ALLFTD** at www.allftd.org.*

WHAT IS FRONTOTEMPORAL LOBAR DEGENERATION?

Frontotemporal dementia (FTD) is a fatal brain disease that is a common cause of neurodegeneration in people under the age of 60. Neurodegeneration means that nerve cells (neurons) shrink, lose connections with other cells, and eventually die. Researchers use the term "frontotemporal lobar degeneration" (FTLD) to refer to the progressive degeneration of the frontal portions of the brain, the regions responsible for language and behavior. This neurodegeneration is often associated with accumulation of proteins in the brain and the reduced ability of brain cells to function normally. This may cause problems with a person's ability to choose and understand words and sentences; a loss of inhibition or empathy; apathy; compulsive behaviors; and changes in diet and eating.

WHAT IS THE ALLFTD STUDY?

ALLFTD is an observational clinical research study. An observational study is one where researchers observe what happens in a disease over time, including the effects of a risk factor, or usefulness of a diagnostic test.

The goal of the ALLFTD study is to enroll individuals with FTLD, those at risk of developing FTLD, and also those not at risk of developing FTLD to observe changes in the brain over time. You do not need to know if you carry an FTLD-causing mutation to participate in ALLFTD. Twenty-three academic centers in the US and Canada serve as ALLFTD sites, so there may be a research site close to you.

Our knowledge about FTLD is based on studies like ALLFTD, which form the foundation for efforts to develop and test possible therapies.

WHAT ARE THE BENEFITS OF ALLFTD PARTICIPATION?

Many of our participants choose to participate in ALLFTD in order to advance understanding of FTLD, which will support the development of therapies. Others participate in order to better understand FTLD as it is experienced in their family and to do something that may help future generations. Still others seek clinical care for persons diagnosed. Whatever the reason for participating, ALLFTD participants receive world-class clinical care and support whether they are at risk, affected, or a care partner.

WHY MIGHT ALLFTD BE IMPORTANT TO YOU?

ALLFTD can provide information on FTLD, insight from expert researchers, support for family members and affected individuals, and counseling on how to navigate changes brought on by FTLD. In addition, by participating in research, you are contributing to the development of future therapies. Because of this, we hope that you might consider connecting with an ALLFTD study coordinator to find out if ALLFTD might be a good fit for you.

WHAT DOES IT FEEL LIKE TO PARTICIPATE IN ALLFTD RESEARCH?

THE FIRST STEP

GIVING YOUR CONSENT

You will be given a document that describes key aspects of the study, as well as information to make sure you understand that your involvement is voluntary and that you can withdraw from the study at any time, without giving a reason. A study coordinator will review the document with you and answer all your questions. The informed consent document must be signed by the participant and can be done online or in-person.

IDENTIFY A STUDY PARTNER TO ACCOMPANY YOU ON VISITS

Your study partner should be someone who has regular contact with you (study participant) and might notice things that you do not. Your study partner can be a spouse or relative or a trusted friend.

THE RESEARCH EXPERIENCE.

These next steps may happen in a different sequence

NEUROPSYCHOLOGICAL TESTING

A researcher will administer a series of memory and critical thinking questions. These questions can make you feel a little stressed; you may feel like you are taking a test back in high school. However, this isn't a test that has right answers. Instead, our researchers are looking for patterns in your answers and want to understand how your cognitive skills are right now at baseline so they can compare the results at another point in time.

MRI

Magnetic resonance imaging (MRI) is a medical imaging technique. For this study, the MRI focuses on your head. The procedure takes about 45-60 minutes. The machine can be loud. If you tend to have claustrophobia, the MRI technicians have techniques to make you feel as comfortable as possible.

LUMBAR PUNCTURE

You may be asked to undergo a lumbar puncture. The lumbar puncture is optional. If you agree, the procedure is performed in your lower back, in the lumbar region. During a lumbar puncture, a small gauge needle is inserted between two lumbar bones (vertebrae) to remove a sample of cerebrospinal fluid. This is the fluid that surrounds your brain and spinal cord. There are biomarkers in your cerebrospinal fluid that can help us understand the progression of FTLD.

VISIT WITH A NEUROLOGIST TRAINED IN FTLD

You will have a clinical visit with a neurologist who will share your research results, including your MRI if the results are available. The neurologist will answer your questions and concerns. The neurologist can also provide information and resources.

BLOOD DRAW

You will undergo a blood draw to look for the presence of possible biomarkers and to analyze genetic information. Biological markers, or biomarkers, are proteins and other substances in the blood that help us understand the progression of FTLD. The day before your blood draw you will be instructed to drink a lot of water and stay hydrated.

GENETIC TESTING

Genetic testing is optional. If you decline, you'll skip this step. If you choose to undergo genetic testing, you'll have an initial visit about your family history. A genetic technologist or counselor will review your family history and create a genetic family tree to help understand the genetic roots of FTLD in your family. Next, a genetic counselor will share information about genetics and the testing process. Learning this information can be extremely sensitive. To ensure that you feel prepared to learn this information, you will meet with a separate counseling team to discuss feelings that might come up during the genetic testing and counseling process. This is a good time to ask your counselor about genetic privacy issues and whether your results will be entered into the clinical record.

Once the test results are available, we will schedule a visit to share those results with you. You will meet with a genetic counselor or counseling team to ensure that you understand the results and have support. At any point in the process, you can change your mind, and even decide not to receive your results at the end of the process.

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FREQUENTLY ASKED QUESTIONS

How Long Does The ALLFTD Visit Take?

The basic ALLFTD visit takes about two and a half days. If you decide to do all the tests and participate in some optional research, the full visit can take four days. Some parts of the research, including the consent and interviews, can be done virtually over the web to reduce your on-site time.

How Long Am I Committing For?

ALLFTD study visits occur once a year and ALLFTD is currently funded through 2025. We hope to receive additional funding to extend the ALLFTD study. In any research study, participation is voluntary. This means that you can stop participation at any time.

Will This Cost Me Anything?

The care or consultations that you receive during the study are free; you may receive compensation for research procedures. In addition, most study costs such as transportation and hotel stays, if required, will be reimbursed by the study. If you have concerns about costs, please speak with the study coordinator.

What Other Resources Are Available To Me?

Available resources differ at each study site. Program coordinators at each site can connect you to resources to help you. Some sites have online groups and support for caregivers or care partners. Please ask your study coordinator to learn what resources are available at your site. A list of study coordinators and their contact information is available at ***www.allftd.org/sites.***

Will Participation In ALLFTD Help Me Access Clinical Trials?

Yes! Our ALLFTD researchers have information about active clinical trials. By participating in ALLFTD, you will be able to learn more about trials and how to participate in them. The research doctor can help you identify a specific trial that may be right for you. Trials for individuals with genetic mutations in *GRN*, *MAPT* and *C9orf72* are currently ongoing. Several more therapeutic approaches are in development and additional trials are expected in the next several years.

May I Participate In ALLFTD And Another Clinical Trial At The Same Time?

Yes! Participation in ALLFTD and a clinical trial at the same time is encouraged. The data learned in both studies is complementary and will help us understand FTLD more deeply. Some sites may be able to coordinate your ALLFTD and clinical trial visits; please ask your study coordinator if you are interested.

What Is The Difference Between FTLD and FTD?

This terminology can be confusing to professionals as well as research participants. "FTD" is an abbreviation for frontotemporal dementia and is used to describe the disease when the symptoms of decline in behavior, language, and/or movement appear. "FTLD" is an abbreviation for frontotemporal lobar degeneration, which describes the brain degeneration that causes the symptoms of FTD.

Additional FAQ may be found at: allftd.org/studyfaq