Alzheimer's Disease Anti-inflammatory Prevention Trial
Participant Consent Statement for Eligibility Evaluation

Purpose

You are being asked to answer some questions and have some tests done. The purpose of these questions and tests is to see whether you are eligible to enroll in the Alzheimer's Disease Anti-inflammatory Prevention Trial (ADAPT). We are talking to you about ADAPT for two reasons. You are 70 years old or older, and you have a father, mother, sister, or brother who has or had dementia, senility or Alzheimer's disease.

ADAPT is a research study being done at The Johns Hopkins University and (local site). It is funded by the National Institutes of Health. The purpose of the study is to test whether certain drugs can prevent Alzheimer's disease. As you may know, Alzheimer's disease is an illness that causes loss of memory and other abilities like language and thinking. The drugs being tested in ADAPT are naproxen (Aleve®) and celecoxib (Celebrex®). Naproxen is used to reduce fever and to treat pain and inflammation from ailments like arthritis. Celecoxib is a new drug for arthritis that works in a similar way but has fewer known side effects. We do not yet know whether either drug will be able to prevent Alzheimer's disease. Recent research suggests that they might, but this idea has not yet been tested. The study may last up to 7 years.

Procedures

To find out if you may enroll in ADAPT, we need to do the following:

- Ask you about your family medical history, your past and present health problems, and the medicines that you take
- Test your memory and thinking abilities; the tests will take about 25 minutes
- Take your blood pressure
- Do a physical exam and test your nervous system
- Collect a urine sample from you to run some tests
- Take 5 or 6 tablespoons of blood from a vein in your arm to run some tests

- Ask the person who came with you about your memory and daily activities
- Ask you for the name of your doctor and permission to contact him or her

After we get the results from the tests, we will know whether you may enroll in ADAPT. If you are eligible and still interested, we will ask you to come back for another visit. At that time, we will tell you more about the study, including its risks and possible benefits. Then you can decide if you want to enroll.

If your blood pressure is high, you will not be able to join ADAPT right away. We will talk to you about ways to treat your high blood pressure. If your blood pressure goes down, then you can join ADAPT. Also, if the results of the laboratory tests are unusual, we may ask you to repeat the tests on another day. This is so we can be sure whether you qualify for the study.

If today's tests show that you do not qualify for the study, we will contact you to let you know why.

Risks/Discomforts

There is a small risk from taking your blood. Sometimes, people feel a slight discomfort or even pain. Some people may feel faint for a few minutes. You might get a bruise on your arm after giving blood. The bruise should go away in a few days.

Today's tests may show that you are having some problems with your memory or thinking. If this occurs, we may refer you for evaluation outside the study.

Benefits

There is no direct benefit from today's tests. However, they are a necessary step if you want to be in ADAPT.

Alternatives to Participation

Your agreement to answer questions and have tests done today is voluntary. You may choose to stop the questions or tests at anytime. Agreeing to today's procedures does not mean that you are agreeing to be in ADAPT. Your choices will not affect the care you receive at this institution. There will be no penalty or loss of benefits to which you are entitled.

Confidentiality

We will make every effort to keep the information you give us confidential. We will not tell anyone without your permission that you are thinking about joining this study. ADAPT staff will use ID codes, not your name or social security number, when recording information about you and your test results. Study files are kept in a secure place. Only people who work on the study will have access to your data.

Questions and Concerns

Before you agree to be tested, make sure that you have answers to your questions. The study site director, Dr. _____, and the staff at ____[phone number]____ will answer any questions you have about this study, now or later.

If you believe that you have been hurt by being tested for this study or that you are not being treated fairly, you may contact the people named above. You also may contact the ___ [name of IRB and Institution] _____ at ___[phone number]___ or The Johns Hopkins University's Office for Research Subjects at (410) 955-3193. The study site director or someone in the offices named above will answer your questions. If necessary, they will help you get medical care if you feel you have been hurt by the study. The Johns Hopkins University, _____[field site]_____, and the Federal government do not have any program to provide compensation for injury or other bad effects that are not the fault of the investigators.

If you agree to answer questions and be tested for this study, please sign your name and write the date below.

_____	_____	_____
Participant signature	Date of signature	ADAPT ID No.
_____	_____	
Witness signature	Date of signature	
_____	_____	
Investigator signature	Date of signature	

Note: The signed consent form must be retained in the participant's file at the study site, and a copy must be given to the participant.