

Research Projects—Should I Participate?

What is research?

Research is a planned method to determine facts in order to answer a question. For example, we do not know everything about Alzheimer's disease and other types of dementias, so there are many unanswered questions. Some topics for research projects try to answer questions about diagnostic tests, treatments, cures, genetics, prevention, the effects of dementia on overall health and welfare, etc.

Why are research studies done?

Often there are "ideas" or "opinions" which seem good. A well-planned and carefully carried out research study answers the questions about an idea or opinion to find out if it really works, changing these ideas or opinions into facts. Research can also prove when something does not work or is harmful.

Why would I want to participate in research?

- You may help yourself, future generations, and society as a whole.
- You are more likely to know the most current information about dementia because you are involved.
- You will have close monitoring during the study.
- You will have access to new drugs and treatments.
- You will meet a new group of people.

Is it in my best interest to participate in a research study?

- Does your physician agree that the research would be beneficial for you?
- The research may find that you have other illnesses, and feedback given to you and your doctor may help in your own medical care.
- You will learn more about yourself.

What information should I expect from the research study center?

- When I need to go to the study center for the first time.
- If I have to interview for eligibility.
- If the project needs to know when I was diagnosed with dementia and what type.
- If it matters how healthy I am or where I live.
- If my caregivers need to participate in the study, too.
- What medical screening tests I will have.

What are the responsibilities of the research study center?

- To be fully informed about research information.
- To be reviewed and monitored by an Institutional Review Board (IRB). The IRB ensures that research is conducted in an ethical manner and that participant rights are protected.
- To tell you what your participation involves.
- To tell you the benefits and risks of the study.

- To tell you who is sponsoring the study.
- To guard your privacy and keep the study confidential.
- To inform you about volunteering for the study.
- To tell you if the study will pay for screening examinations, medication, and follow-up examinations. (Most studies pay for these items.)

What are my caregivers' responsibilities if I participate?

- Allow for a serious time commitment from both the person with dementia and the caregiver.
- The caregiver usually gives the research medication to their loved one and reports any changes in them such as insomnia, constipation, drowsiness, etc. that may result from the use of the new drug.

Types of studies

Many different kinds of research studies are available for people who have some form of dementia.

Examples:

- Tests of new medications
- Diagnostic interviews and testing
- Dementia rating systems
- Testing for the structure and the function of the brain of the person with dementia
- Driving and dementia
- Blood and urine sample testing, looking for the cause of Alzheimer's disease
- Caregiver stress in caring for someone with dementia

Clinical trials determine the effectiveness and safety of a drug

Volunteering for a drug research project may involve some risk. The treatments being tested are experimental. However, by the time researchers begin testing a new drug on people, they are fairly sure that the drug will yield positive results with few harmful side effects. There is a chance that the drug will be helpful to you. In case the drug causes discomfort, you can drop out of the study at any time.

Only some of the participants in a drug study get the medication being tested

In almost every study, participants are divided into two groups—an experimental group (which receives the new drug) and a control group (which receives a placebo, or sugar pill). Neither the participants nor the researchers know who is taking the real drug and who is taking the placebo. A different person collects data for the study, records this information, and releases it to the researchers and participants when the study is completed. This type of study design—a double-blind, placebo-controlled study—lets researchers compare the effects of the real drug to the effects of a placebo without allowing their personal opinions about the drug to influence observations during the study.

Participants who receive a placebo are as important as those receiving the experimental drug

If you get a placebo, you may still benefit from the increased medical attention. Clinical drug studies *cannot* be completed without a placebo group. Often, after a study has yielded positive results with few reported side effects, members of the placebo group are given the option to receive the experimental drug.

What if I have questions about the research project?

In the enrollment process, it is important to *ask questions*. Ask for clarification about the study, what will be involved as it progresses, and *anything* that makes you feel uncomfortable about participating. The researcher should be able to answer any questions you may have during the study. If you are not satisfied with the answers at any time, it may be best to stop participating in the study.

Remember, not everyone will be willing or eligible to become a research participant. But for those who do participate, there is the satisfaction of being involved in the development of a potential treatment for Alzheimer's, as well as the possibility that the experimental drug or coping strategies may benefit the individual with the disease and their caregivers.

How do I find out about research studies?

Alzheimer's Association TrialMatch™: The Alzheimer's Association recently launched "a free service that makes it easy for people with Alzheimer's, caregivers, families and physicians to locate clinical trials based on personal criteria (diagnosis, stage of disease) and location... More than 100 research studies pertaining to Alzheimer's disease and related dementias are underway and recruiting volunteers." You may also wish to view the 2 minute video About Alzheimer's Association TrialMatch.

The Alzheimer's Association—St. Louis Chapter has two lists of local research studies:

- Research Projects—Open for Participation: non-drug studies that focus more on coping with dementia, developing strategies for caregivers to use and genetic issues.
- Research Drug Studies—Open for Participation: list of all drug trials currently enrolling participants in the St. Louis area

Call and ask about research studies (or visit the websites):

- St. Louis University, Department of Neurology & Psychiatry: 314-577-8711
- Alzheimer's Disease Research Center (Knight ADRC): 314-286-2683
- University of Missouri, St. Louis, Department of Psychology: 314-516-5391
- Clinicaltrials.gov (U.S. National Institutes of Health)

Other helpful fact sheets and information:

National Alzheimer's Association

Participating in Alzheimer's Disease Clinical Trials and Studies Fact Sheet from the Alzheimer's disease Education and Referral (ADEAR) Center (no link)

Taking Part in Research Studies: What Questions Should You Ask? from the Centers for Disease Control and Prevention (CDC)

Understanding Clinical Trials from ClinicalTrials.gov