



THE AGING & ALZHEIMER'S UPDATE

PUBLISHED BY THE LAYTON AGING & ALZHEIMER'S DISEASE CENTER
A NATIONAL INSTITUTE ON AGING ALZHEIMER'S DISEASE CENTER

FEBRUARY 2008

Why do people volunteer to be research subjects?

Each year, many thousands of people volunteer to be research subjects in studies that are searching for the causes of Alzheimer's disease and ways to treat and prevent it. Depending on the research objectives and study design, research subjects may be people with Alzheimer's disease or mild cognitive impairment; they may be relatives of persons with Alzheimer's disease concerned that they are at risk for developing Alzheimer's disease; or they may be healthy adults without any symptoms of cognitive impairment. It is worth stepping back and asking the question, "Why do people volunteer for research?" The answer is that there are many reasons. For some people, studies are a means to access new potential treatments. Study-



related medical care such as physical exams, lab tests, counseling, and study medication is often provided at no cost to the participant. Many study volunteers appreciate the close medical attention they receive, often from a trusted clinician, as part of the study. People may also get involved in a study because they want to help in the advancement of medical knowledge and have the satisfaction that they are helping others. Barbara Carlin, who has participated in the Layton Center's Oregon Brain Aging Study for about 13 years, explained how she became interested: 'I first

Continued on page 2 . . .

Barbara Carlin, healthy research volunteer in the Oregon Brain Aging Study, Layton Aging & Alzheimer's Disease Center.

Why Do People Volunteer . . .

Continued from front page

volunteered for the Oregon Brain Aging Study when I was retired, my husband had died, and my children had all moved away. This was my chance to do something that I really am interested in. I have always been interested in why people think like they do and why some people's minds work differently than others.'

The decision to enroll in a study

Dr. Jason Karlawish at the University of Pennsylvania Alzheimer's Disease Center has studied how Alzheimer's patients and their caregivers decide to enroll in clinical trials. He found that for many patients and caregivers the decision to enroll in a study is made relatively easily and quickly. In these cases, both the patient and the caregiver agree with the decision to enroll in the study. When a decision has been made not to enroll, Dr. Karlawish found that the caregiver and the patient were often in disagreement about whether or not to enroll.

The decision to enroll in a study involves an assessment of the benefits of participation weighed against the time, possible inconvenience of participation, and the possibly uncomfortable procedures. In recent work, Dr. Karlawish asked older adults about their willingness to participate in a hypothetical research study based on the degree of risk, chances of receiving the experimental drug, and the convenience of the study visits (i.e., either research visits were made to the subject's home, car service was provided to the research site, or subjects had to visit the research site but no transportation provided). As one might expect, these factors influenced people's willingness to participate. For the study scenario with low risk, home visits, and two times the chance of receiving the experimental drug rather than the placebo, 60% reported a willingness to participate. For a study scenario with high risk, required visit to the research site, and an equal chance of getting the experimental drug or not getting it, only 17% reported a willingness to participate.

Things you should know about research participation

Participation in a clinical research trial is completely voluntary. Privacy and safety are of utmost concern for the researchers, their staff, the institution and the IRB. Two groups oversee the safety of research studies at OHSU: the organization that sponsors the study (e.g., National Institute on Aging at the National Institutes of Health) and the OHSU Institutional Review Board (IRB). Prior to participation, volunteers are asked to sign an informed consent and a HIPPA document that explains how data is used and with whom it can be shared. The informed consent has specific, detailed information about the study in non-medical language. It assures research volunteers that they may withdraw at any time from the study. Signing the consent form means that the study volunteer has been informed about the study and agrees to participate. Signing does not indicate that the volunteer has signed away any rights. The volunteer is always free to stop participating in some portion or all of the study at any time. The IRB pays particular attention to studies that involve persons with cognitive impairment such as Alzheimer's disease to ensure that they are able to consent to the study or that a family members or other responsible person agrees to their participation. ❁

For further information on participating in research, check out these websites:

www.ohsu.edu/research
<http://clinicaltrials.gov/ct/gui>

Karlawish JHT, Casarett D, Klocinski J, & Sankar P. How do AD patients and their caregivers decide whether to enroll in a clinical trial? *Neurology*, 56(6), 2001, 789-792.

Karlawish, J, Cary, MS. Home visits may improve recruitment in AD clinical trials. *Alzheimer's & Dementia*. 2007; 3(3): S171-S172. Presented at the Alzheimer's Association's 2007 International Conference on Prevention of Dementia, Washington, DC, June, 2007.

EDUCATION OPPORTUNITIES

OHSU Brain Awareness

Lecture Series 2008

(7 pm, Newmark Theatre,
downtown Portland)

FEBRUARY 11

In Search of Memory: The Emergence of the New Science of Mind

Eric Kandel, MD,

- Columbia University

FEBRUARY 19

The Developing Human Brain: What is normal and What is Not

Pat Leavitt, PhD

- Vanderbilt University

FEBRUARY 25

The Sleeping Brain: How Sleep Affects Mood, Memory and Behavior

Al Lewy, MD, PhD

- OHSU

MARCH 3

The Brain and Gender: Sex Differences Do Matter

Larry Cahill, PhD

- UC Irvine

Pre-registration required:

503-494-0885

or www.oregonbrain.org

SAVE THE DATE!

**10th Annual McGinty conference
April 17, 2008**

***“Hope for Tomorrow,
Help for Today”***

www.alz.org/oregon

The ORCATECH Living Laboratory: A Special Group Of Research Volunteers

Nicole Larimer, Point of Care Lab Project Coordinator, OHSU

The Oregon Center for Aging & Technology (ORCATECH), a collaboration of over 40 public and private organizations including the NIA-Layton Aging & Alzheimer’s Disease Center, the OHSU Oregon School of Science and Engineering, Intel, senior housing providers, and local technology companies have come up with a novel and successful approach to engaging seniors in technology research. The ORCATECH “Living Laboratory” is a group of community-dwelling seniors who have agreed to participate on an ongoing basis in research on technology-based health monitoring and interventions focusing on maintaining independence.

ORCATECH, with support and funding from the National Institute on Aging Roybal Center at OHSU and Intel, came up with the idea of “The Living Laboratory” to address some of the many challenges of carrying out this complex, time-consuming, and costly research. Testing new technologies in homes is important because it provides feedback on the devices in real world conditions. The cost and time involved in installing the equipment needed for testing new technologies in homes is not insignificant, so being able to install the equipment and use it for multiple purposes is an efficient strategy.

The Living Lab cohort currently consists of older adults who live in 14 homes. This will expand to 30 homes around the Portland metropolitan area by the end of February 2008. Each home is being installed with a core set of technologies that includes:

- Infrared motion sensors to estimate activity in the home and to measure speed of walking.
- Door sensors to estimate activity occurring outside of the home.
- RFID location tags to determine who is moving through the space.
- Bed mats and/or load cells for assessing restlessness and activity in bed.
- A home computer, from which daily use measures (time spent in email, web surfing, word processing) and motor measures (e.g., the time intervals between keystrokes, the number of steps taken with the computer mouse to reach a target) are taken.
- A small computer used to collect and transmit data to the research center using broadband internet.

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In addition, most homes have the following:

- A medication tracking device, to assess medication taking habits of participants.
- A kiosk interface, which includes a handset on the home computer, through which a short weekly automated cognitive test is administered.

Most of the core technologies integrates easily into the lives of the participants. As new technologies are introduced, participants provide feedback about what they like and dislike, how we might make it easier to use, and if they feel it is useful.

Variation among the Living Lab participants and their homes is a hallmark of this special group of research volunteers. Participants range from 65-90 years old. Some are married, some single. They live in retirement



Elly Steacy, Living Lab Study Subject, using the medication tracking device.

communities, condos, apartments, duplexes and single family homes. Several have many years of computer experience; others have never even used a cell phone. There are people in perfect health and others with a variety of health conditions. It is this

mixture that helps us explore how different conditions affect technologies – including how different people use or interact with the same technology.

Because we wanted a variety of different living environments in our Living Lab, we recruited people in the general community. Some people had previously contacted us about participating in our studies. Others had seen news stories about our research, like Helen Mason who said, “My daughter saw a notice in the San Francisco paper about the study and called me. I felt that perhaps I could volunteer for an interesting program without leaving my home, on my time.”

An overarching theme in why people have chosen to participate in this research is their desire to help ORCATECH be successful in its search for technology-based solutions that will enable seniors to live independently as long as possible. Participant Sulima Malzin explains, “Maintaining independence in my elder years is important to me; so to be able to assist in the development of technologies that help that happen just made sense.” Other factors influenced the decision to participate as well: family members with a history of memory problems, a new computer (including computer instruction if needed), and free high speed internet for the duration of the study.

Whatever their reasons, we have a great appreciation for these people who make up the Living Lab – it wouldn't exist without them! ❁



Support Alzheimer's research by making a donation through your Oregon income tax form.

For information about the Oregon Alzheimer's Research Tax Check-Off Program, contact Linda Boise (boisel@ohsu.edu) or 503-494-6370.



WHAT IS A CLINICAL TRIAL?

Many research studies are randomized clinical trials. This means that research subjects will be assigned in a random way to either receive the drug being tested or a “placebo” which appears to be the drug being tested but in fact is not. A “double-blind randomized control trial” means that the researchers do not know which subjects receive the experimental drug and which receive the placebo until after the data has been collected from the trial. This procedure prevents researchers or their analysts from influencing the results because of what they would like to see or think will happen.

Clinical research trials are conducted in four phases. Each phase is a separate study. One volunteer rarely participates in more than one phase of the same trial.

PHASES OF CLINICAL TRIALS

Phase I Trials: A phase I trial is the first use of a new drug in humans. The new experimental therapy is tested in a small, healthy group of people to assess the safety of the drug and any side effects.

Phase II Trials: the new experimental therapy is tested in a relatively small group of people who have the disease or condition for which the therapy was developed. Safety and effectiveness are evaluated.

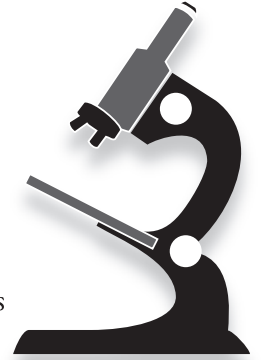
Phase III Trials: A large number of people are enrolled in a randomized trial to compare the new experimental therapy versus standard therapy/care. If successful, the results from these trials will be used to gain approval by the Federal Drug Administration (FDA) for general use.

Phase IV Trials: With FDA approval for general use, this phase involves on-going studies of the safety and effectiveness of the therapy.

New Clinical Trials For 2008 Will Build On Knowledge Gained From Earlier Successful Research

Joseph Quinn, MD, Neurologist and Director, Biomarker and Genetics Core, Layton Aging & Alzheimer's Disease Center

When Dr. Alzheimer looked through the microscope at the brain of his first patient, he saw two things: “plaques” and “tangles”. These microscopic brain lesions are still the foundation of the definitive diagnosis of Alzheimer’s disease at autopsy. Many scientists think that these lesions are responsible for the slow degeneration of brain and mind in patients with Alzheimer’s, and a great deal of research has focused on them over the past 20 years. These studies have shown that the “plaque” is composed of a substance called “beta-amyloid”, and many scientists believe that abnormal forms of beta amyloid are toxic to the brain, and in fact drive the deterioration seen in the brains of patients with Alzheimer’s disease. This theory is called the “amyloid hypothesis”, and experimental treatments based on this theory are called “anti-amyloid” treatment strategies.



There are basically two ways to reduce beta amyloid in the brain: reduce beta amyloid production or promote beta amyloid removal. The “reduce production” strategy is being tested in one clinical trial currently under way at OHSU using a drug called “flurizan”. That trial is currently closed to enrollment, and results are expected by the end of 2008. A trial of a similar drug is about to be launched at OHSU with a drug known as a “gamma secretase inhibitor.” Doctors at OHSU had participated in the pivotal trials developing this drug as one of only 6, which was promising enough to warrant a larger trial.

The “promote beta amyloid removal” approach is also under study at OHSU. A study of a drug which is actually a synthetic antibody to beta amyloid is going to be launched in early 2008. Again, this study is based on favorable results of an earlier trial conducted in part by OHSU doctors, which showed that this antibody could be administered safely in patients with mild Alzheimer’s disease. The new study will test larger numbers of subjects to determine if the antibody actually slows down the rate of progression of Alzheimer’s. ❄

To find out more about the research studies discussed in this newsletter or about other research and clinical trials at the [Layton Aging & Alzheimer's Disease Center](#), check our Web site (www.ohsu.edu/research/alzheimers) or call Joyce Lear at 503-494-7615.

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OHSU

OHSU includes the schools of dentistry, medicine, nursing, and science and engineering;
OHSU Hospital and Doernbecher Children's Hospital; numerous primary care and specialty clinics;
multiple research institutes; and several outreach and community service units.

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