

## UCSD School Of Medicine Is Coordinating Center For National Alzheimer's Neuroimaging Initiative

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The University of California, San Diego (UCSD) School of Medicine will be the Coordinating Center for a nationwide \$60 million, 5-year public-private partnership called the Alzheimer's Disease Neuroimaging Initiative. Announced today by the National Institute on Aging (NIA) in conjunction with other Federal agencies, private companies and organizations, the Alzheimer's Disease Neuroimaging Initiative will test at 50 sites in the United States whether serial magnetic resonance imaging (MRI), positron emission tomography (PET), other biological markers, and clinical and neuropsychological assessment can be combined to measure progression of mild cognitive impairment (MCI) and early Alzheimer's disease (AD).

The Coordinating Center at UCSD is directed by Leon Thal, M.D., UCSD chairman, Department of Neurosciences, director of the UCSD Alzheimer's Disease Research Center, and director of the national Alzheimer's Disease Cooperative Study (ADCS). In 2001, the NIA awarded \$54 million to UCSD for coordination of clinical drug trials by a consortium of Alzheimer's research centers around the country.

The new neuroimaging study could help researchers and clinicians develop new treatments and monitor their effectiveness as well as lessen the time and cost of clinical trials. The project is the most comprehensive effort to date to find neuroimaging and other biomarkers for the cognitive changes associated with MCI and AD.

Within the Federal Government, the NIA is joined in the partnership by another National Institutes of Health (NIH) Institute--the National Institute of Biomedical Imaging and Bioengineering (NIBIB) -- and by the Food and Drug Administration, all of which are part of the U.S. Department of Health and Human Services. The Foundation for NIH is managing corporate and other private participation, and has received commitments totaling more than \$20 million in contributions from the following companies and organizations: Pfizer Inc, Wyeth Research, Eli Lilly and Company, Merck & Co, Inc., GlaxoSmithKline, AstraZeneca AB, Novartis Pharmaceuticals Corporation., Eisai Global Clinical Development, Elan Corporation, plc, the Institute for the Study of Aging (ISOA) and the Alzheimer's Association. About two-thirds of the funding is expected to come from the Federal Government while private partners are expected to make up the other third. Ancillary studies will be funded by additional NIH grants.

"This is an extraordinary pooling of talent and resources toward a common goal -- delaying or preventing Alzheimer's disease," says Richard J. Hodes, M.D., Director of the NIA.

"The initiative should become a landmark study in the development of neuroimaging and other biomarkers, helping us to find biological changes early so that we can identify the people at highest risk of the disease and test the effectiveness of new therapies more quickly and efficiently."

The study will take place at approximately 50 sites across the U.S. and Canada, including studies at UCSD under the direction of Adam Fleisher, M.D. In April 2005, investigators will begin recruiting about 800 adults, ages 55 to 90, to participate in the research -- approximately 200 cognitively normal older individuals to be followed for 3 years, 400 people with MCI to be followed for 3 years, and 200 people with early AD to be followed for 2 years.

The study will compare neuroimaging, biological, and clinical information from these participants, seeking correlations among the data that will track the progression of memory loss from its earliest stages. Neuroimaging research has suggested that PET or MRI may serve as a more sensitive and consistent measure of disease progression than the neuropsychological and cognitive assessments now typically used in research and clinical practice. As MCI and AD progress, for example, areas of the brain involved with memory, such as the hippocampus (a part of the brain heavily involved in memory), shrink.

Using the high resolution images produced by MRI, researchers will evaluate the best ways of measuring this volume loss in the hippocampus and other brain structures. PET scans assess brain function by measuring the rate of metabolism of glucose, the brain's fuel. PET scans of people with AD show that glucose in certain parts of the brain is metabolized at lower levels than in healthy people, and previous studies have shown that low glucose metabolism can be seen in some people even before noticeable symptoms of memory loss occur. The Initiative will seek to identify additional biological factors from blood, cerebrospinal fluid (CSF), and urine samples.

"The key challenge here is to identify critical markers that respond to treatments aimed at slowing the progression of mild cognitive impairment and Alzheimer's disease," says Michael W. Weiner, M.D., the study's Principal Investigator. \* "For example, today, imaging is used to rule out other causes of memory problems, still not leaving the researcher or the clinician with a very clear idea of what is going on. By the end of this study, we should be able to use imaging and other biomarkers to accurately monitor disease progression and detect the effects of treatments which can slow that progression."

Information about the participating research sites and co-investigators leading various aspects of research may be obtained from the NIA. While recruitment for the study will not begin until spring 2005, people interested in participating in the study can contact the NIA's Alzheimer's Disease Education and Referral (ADEAR) Center at 1-800-438-4380 for additional information.

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