DATE: March 22, 2012
SUBJECT: Common informed consent form for AD clinical studies

The Problem

The final report of the Alzheimer's Study Group emphasized that patients are critical contributors to clinical development. There was a call for patients to be made aware that they can speed the search for new treatments by enrolling in clinical trials, contributing tissue samples, and allowing the use of their medical records for research. Human subjects, research funding, and time are all in limited supply. Clinical research on Alzheimer's Disease (AD) must develop methods to assure that resources are used wisely and strategically. The informed consent form is a good place to start.

Currently, patients sign an informed consent form for a single study and specific purpose, rendering the data useless as other ideas become promising. As a result, data are essentially lost and new studies have to be conducted resulting in additional expense, delays and more patients subjected to experimental trials. Even though data sharing is a requirement in NIH funded studies, misunderstandings and overly restrictive consent forms restrict access to data collected under NIH funding and industry clinical trials as well.

The Solution

Obtaining de-identified data from AD clinical trials, multicenter and single site studies, and pooling these data to build large databases is a critical step in providing the necessary research infrastructure to gain an understanding of a disease as complex as Alzheimer's and to examine significant scientific issues such as biomarkers.

Recommendation

We recommend a mechanism to let Alzheimer's patients allow their de-identified data be used for research purposes broader than a single study and that advance understanding, treatment and prevention of Alzheimer's disease. We recommend allowing pooling of individual de-identified data into larger AD databases to allow datamining and increase statistical significance, provide information on the natural history of AD, identify promising biomarkers and response or non-response to treatment. This database would need to address privacy, informed consent and liability issues and need a mechanism to protect proprietary and confidential data. Research activities involving human participants will continue to be conducted in a way that promotes their rights and welfare but include a feature for allowing Alzheimer's patients to opt in and contribute their de-identified data for research as in public databases or opt out for those who do not want to allow their data to be used for research purposes.

The National Health Council has conducted surveys and issued reports such as the Electronic Health Information Exchange: A Live Strong Report describing that "87 percent of patients strongly agree that EHR should provide patients with a way to share their medical information with scientists doing research – as long as the information cannot be linked to them personally."