



“A Multicenter Vitamin E Trial in Aging Persons with Down Syndrome”

The Institute for the Study of Disadvantage and Disability (ISDD) has been selected as a site to participate in a multicenter Vitamin E trial in aging persons with Down syndrome. This project continues as the first large-scale treatment study of Alzheimer disease in persons with Down syndrome. The granting project sponsor is the National Institutes of Health (NIH).

Dr. Leslie Rubin in collaboration with **ISDD** located at 776 Windsor Parkway, Atlanta, GA is recruiting persons with Down syndrome over the age of 50 to participate in this important study.

It is known that people with Down syndrome over the age of 50 are more likely to get Alzheimer disease than other older people. Some of the changes that occur in people who develop Alzheimer disease include a decline in memory, thinking, working, and self-help skills. Vitamin E has been shown to slow the development of these changes in some people with Alzheimer disease in the general population. We do not know, however, whether it will help older people with Down syndrome. By giving some people a high dose of Vitamin E and other people inactive pills called placebos, we aim to find out whether Vitamin E really helps to slow the rate of cognitive/functional decline in older individuals with Down syndrome as they grow older.

Individuals with Down syndrome over the age of 50 with or without a diagnosis of Alzheimer disease will be recruited from their homes or from state and private service provider agencies. A Vitamin E regimen of 1,000 I.U. (international units) twice daily, plus a multivitamin will be compared to a placebo and multivitamin. The treatment period will be for three years, with study visits at six-month intervals and telephone contacts at 3-month intervals in between. For an individual to be considered, a "Consent to Participate in Research" form must first be signed by either the individual or their legal guardian. An initial Screening Visit will be scheduled close to where the individual lives to determine if he or she will be eligible. During this visit, basic information about the person's health, medical, social, and work background will be gathered and a brief physical examination will be done. A blood sample (about 2 tablespoons) will also be collected, and the participant will be asked to perform a brief praxis test, which is a series of simple fine and gross motor tasks that will evaluate one's ability to make simple voluntary movements and handle two common objects (a padlock and a small jar). Each selected study participant will be seen every 6 months for 3 years. A 6-month supply of either Vitamin E or placebo pills that look like the Vitamin E will be supplied during each follow-up visit. A supply of multivitamin supplements will also be

