Alzheimer’s Patients Participating in Research Studies

by BRENDA VANTA

Alzheimer's Clinical Trials

In order to participate in Alzheimer's clinical trials, an individual must be able to sign a valid informed consent. That individual must be capable of making informed decisions in order to sign the consent form. What if an individual’s ability to think and to make decisions has been impaired, as happens in Alzheimer’s disease?

Surrogates (Substitute Decision Makers, SDM)

Alzheimer’s patients must have a surrogate (SDM) to make decisions on their behalf. A surrogate is usually a spouse, child, caregiver or other trusted person who will make everyday decisions, including medical choices, on behalf of a person with Alzheimer’s. The surrogate can also have the Alzheimer’s sufferer involved in a research study. The Alzheimer’s Association provides some general guidelines for surrogates and answers some very important questions; for example, when is it appropriate for a surrogate to enrol individuals with Alzheimer’s in a study? What is the optimal risk/benefit ratio to be considered when making the decision to have an Alzheimer’s patient participate in a study?

Assessing the Risks

A research study can involve *minimal risk* or *greater than minimal risk* research. Minimal risk research involves observation of the Alzheimer’s patient, who will undergo a diagnostic review, blood tests or imaging tests such as CT scans or MRIs.

On the other hand, greater than minimal risk research would, for example, be a surgery or a procedure that is potentially associated with serious adverse reactions.

General Guidelines

All individuals with Alzheimer’s should be allowed to enrol in minimal risk clinical trials, even studies in which there are no potential benefits to the patient. The risks are very low while the research findings can potentially help many future patients.

For greater than minimal risk of studies, which show reasonable benefits to a patient, the participation of people with Alzheimer’s is allowed if a substitute decision maker provides consent.

For greater than minimal risk of studies that may not provide reasonable benefits to the patient, the enrolment is restricted to only those who (a) are capable of giving an informed consent themselves, or (b) have advanced directives specifically addressing the participation in a study. In other words, the substitute decision maker can’t provide consent for the patient, but he or she should be available to monitor the patient during the study.

Considerations

A surrogate can help the patient consent to a treatment or procedure. For example, if an Alzheimer's patient refuses a blood test out of frustration, they may be willing to comply at a later time, once a surrogate or a family member helps them to calm down. If the patient is continuously refusing the treatment, he can withdraw from a study even if the surrogate believes the research should continue.