WHAT IS A CLINICAL TRIAL?

A clinical trial is a research study of a potential new medication or new use for an existing medication. In dementia clinical trials, procedures such as physical and neurological exams, MRIs, ECGs and cognitive assessments are often used to evaluate medications. The information collected during a clinical trial is essential for determining whether a medication will be approved by the U.S. Food and Drug Administration (FDA). On average, 12 years and millions of dollars are invested before a medication is made available to the public.

Many steps are completed before testing of an investigational medication in human volunteers. Pharmaceutical companies first develop the study medication and then select physicians, called investigators, who are qualified to conduct the clinical trial according to a strict protocol. Clinical trials are conducted under the oversight of an Institutional Review Board (IRB). IRBs are independent committees that review the research protocol.
WHY SHOULD I JOIN A CLINICAL TRIAL?

There are many reasons to participate in a clinical trial. You may volunteer in the hope that you will personally benefit. Participation in research may provide access to a type of investigational medication. You may also volunteer for altruistic reasons – you may wish to help others and advance medical science.

Throughout the study, you will be assessed and supervised by a physician and other research professionals.

WHAT CAN I EXPECT IN A CLINICAL TRIAL?

Before entering a study, you will receive a detailed description of your specific clinical trial and what is expected of you. Your medical history will be reviewed and a thorough evaluation of your condition (including a physical exam and laboratory tests) will be performed. As a volunteer, your privacy is protected and your medical records remain confidential. Of course, with your written permission, the results of our evaluations can be sent to any of your regular physicians.

During the study we will ask you to report any symptoms you experience no matter how minor they seem to you. Anytime you have a question during the course of a clinical trial, you will have the opportunity to discuss your concerns with the investigator or another staff member. As a volunteer, you have the right to withdraw from the study at any time and for any reason.

WHAT HAPPENS AFTER THE CLINICAL TRIAL?

When a clinical trial ends, several things may happen. Sometimes, the company sponsoring the trial continues to provide the study medication to those volunteers who are responding well. Other times a volunteer will stop receiving the study medication when the trial is over. The specific plan for your study will be explained to you by our staff. Please ask if you have any questions.

Our investigators will explain what treatment is recommended for each individual volunteer after the trial is completed. We will endeavor to help you get a good treatment plan in place.