

Name of Study: Oxcarbazepine versus Placebo in Childhood Autism

Location: University of Medicine and Dentistry- Robert Wood Johnson Medical School, Department of Child and Adolescent Psychiatry, 671 Hoes Lane West Piscataway, NJ 08854

Eligibility Criteria: Ages between 5 and 17 with an Autism Spectrum Disorder

Principal Investigator: Sherie L. Novotny, M.D

Contact Information: Annie Kutlik, Research Coordinator, (732) 235-5690

Dear Parent,

I am writing this letter to offer your child an opportunity to participate in a research study at the Department of Child and Adolescent Psychiatry, Robert Wood Johnson Medical School. The study is designed to assess the effectiveness of treatment with Oxcarbazepine vs. placebo in childhood/adolescent autism. The study is looking to see the effects of Oxcarbazepine (currently FDA approved as monotherapy for adults and as adjunctive therapy for partial seizures in epileptic children aged 2 to 16 years of age) in acute treatment of global autism severity, on improving functional ability, decreasing irritability and aggression and in decreasing mood instability. We are recruiting children ages 5-17 with an Autism Spectrum Disorder. The study takes place over eight weeks. It involves a series of diagnostic assessments, blood work, urinalysis and ECG. The children will undergo baseline diagnostic and IQ testing prior to being randomized into a 12-week, double-blind (participants will receive either medication or placebo (sugar-pill), but neither investigator nor participant will know which was received), placebo-controlled treatment study with Oxcarbazepine. The patients will be seen regularly and will be assessed for medication response on different parameters such as irritability, aggression and mood instability using standardized rating scales.

For their participation, medication will be provided at no cost. Transportation costs will not be provided however can be arranged if necessary. There is no charge to participate in the study. For more information about study participation, please contact Annie Kutlik, our research coordinator, at (732) 235-5690. Thank you in advance for your time and assistance.

Sincerely,

Sherie L. Novotny, M.D

Department of Child and Adolescent Psychiatry

University of Medicine and Dentistry- Robert Wood Johnson Medical School