

Name of Study: Drug study for the treatment of irritability and related behaviors in children and adolescents with Autistic Disorder

Location: Fay J. Lindner Center for Autism and Developmental Disorders, North Shore-Long Island Jewish Health System, 4300 Hempstead Turnpike, Bethpage, New York 11714

Eligibility Criteria: Males and females between age 5 and 17 with a body weight of at least 20 kg. The child must meet current *DSM-IV-TR* diagnostic criteria for Autistic Disorder (other diagnoses on the spectrum are not eligible) and also demonstrate irritability and related behaviors. There are some exclusions relating to scores on diagnostic tests, other medical conditions, health issues, etc. Please contact us directly for any questions regarding exclusions. Also, we are looking for families who are willing to drive to our site in Bethpage, NY, and can comply with the visit structure listed below.

Principal Investigator: Dr. Joel Bregman

Contact Information: Linda Spritzer, Research Assistant, phone: (516) 802-8608

Dear Parent,

I am writing this letter to offer your child an opportunity to participate in a research study at the Fay J. Lindner Center for Autism. This study will test the safety and effectiveness of lower doses of a study medication already approved for the treatment of behavioral symptoms associated with Autism.

The study lasts for 6 weeks and you will be asked to attend the clinic in person with your child for study visits. Various evaluations, assessments and tests will be collected at each study visit and your child will be carefully monitored by the study doctor.

If your child completes this study there is the option for your child to enter a 26-week trial phase of and the study medication.

There is no charge to participate in the study and you will be reimbursed for travel and time expenses.

If you are interested in learning more information about participating in this study, please contact Linda Spritzer, Research Assistant at (516) 802-8608.

Sincerely,

Dr. Joel Bregman, M.D., Medical Director, and research staff
Fay J. Lindner Center for Autism and Developmental Disorders (North Shore- Long Island Jewish Hospital System)