

***THIS STUDY NO LONGER RECRUITING***

**Name of Study:** A Multicenter, Double-Blind, Randomized, Placebo-Controlled, Parallel-Group Study with Three Fixed Doses of a Study Medication in Children and Adolescents with Autistic Disorder

**Location:** Health Sciences America, Boca Raton, Fl, USA

**Eligibility Criteria:** Children with a mental age of at least 18 months with Autism, demonstrating behaviors such as tantrums, aggression, self-injurious behaviors, or a combination of all these. Ages 6 through 17 years

**Principal Investigator:** Dr. Greg Marsella

**Contact Information:** Mr. Christopher Castronova, Research Coordinator, (561) 674-5290

Dear Parent,

I am writing this letter to offer you and your child an opportunity to participate in a research study at Health Sciences America. The purpose of this study is to look at the safety and effectiveness of different doses of an investigational medication compared to placebo (medically inactive substance) in children and adolescents ages 6 to 17 who suffer from Autism with serious behavioral problems and who have a mental age of at least 18 months.

The study takes place over eight weeks. It involves cognitive testing and rating scales to assess behavioral problem severity. Toys are available for children to use while the parents work with the doctor on completing the scales. Mental age assessments may be given if they have not already been obtained. The Autism Diagnostic Interview-Revised (ADI-R) will be given to every child.

There is no charge to participate in the study.

If you are interested, please contact Christopher Castronova, one of our research coordinators, at (561) 674-5290.

Thank you in advance for your time and assistance. We look forward to working with you in the near future.

Sincerely,

Dr. Greg Marsella  
Health Sciences America