

THIS STUDY NO LONGER RECRUITING

Name of Study: Risperidone in the Treatment of Children and Adolescents With Autistic Disorder: A Double-Blind, Placebo-Controlled Study of Efficacy and Safety (GCO#: 08-0219, IRB approved through 3/17/2009)

Location: The Seaver and NY Autism Center of Excellence at Mount Sinai School of Medicine, New York, NY

Eligibility Criteria: Children ages 5-17 who meet current criteria for DSM-IV diagnostic criteria for Autistic Disorder and display aggression and irritability. There are some exclusions; please contact the coordinator directly to see whether your child meets eligibility requirements.

Principal Investigator: Dr. Eric Hollander

Contact Information: Jessica Kiarashi, Research Coordinator; phone (212) 241-7098

Dear Parent,

I am writing this letter to offer your child an opportunity to participate in a research study at the Seaver and NY Autism Center of Excellence at the Mount Sinai School of Medicine.

This study is a placebo-controlled treatment trial of Risperidone targeting aggression, irritability, tantrums, and self-injurious behaviors in children with Autistic Disorder.

Risperidone is already approved for the treatment of behavioral symptoms associated with Autism, but this study is testing the safety and effectiveness of Risperidone at lower doses. We are recruiting aggressive children and children who hurt themselves ages 5-17.

The study takes place over six weeks. It involves weekly visits with the study doctor to monitor the progress and safety of your child. For your participation, you will receive reimbursement.

There is no charge to participate in the study.

If you are interested in participating, please contact Jessica Kiarashi, the clinical research coordinator, at (212) 241-3692.

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

Sincerely,

Dr. Eric Hollander

Esther and Joseph Klingenstein Professor and Chairman of Psychiatry

Director, Seaver and New York Autism Center of Excellence at Mt. Sinai School of Medicine