

THIS STUDY NO LONGER RECRUITING

Name of Study: An Open-Label, Flexible-Dose Evaluation of the Safety and Tolerability of STX209 for Treatment of Irritability in Subjects with Autism Spectrum Disorders

Location: Yale University Child Study Center, New Haven, CT

Eligibility Criteria: Children and Adolescents ages 6 through 17 years with Autism Spectrum Disorders including Autism and Pervasive Developmental Disorder Not Otherwise Specified (PDD-NOS)

Principal Investigator: Lawrence Scahill, MSN, PhD

Contact Information: Allison Gavaletz, Study Coordinator, phone (203) 785-6669; email allison.gavaletz@yale.edu

Dear Parent,

I am writing this letter to offer you and your child an opportunity to participate in a research study at Yale University. The purpose of this study is to determine if an investigational medication called STX209, or R-baclofen, is safe and tolerable. This study will also look at whether STX209 is helpful in treating moodiness, irritability, tantrums and aggression in children with Autism or PDD-NOS.

If eligible, your participation in this study will last up to 18 weeks. Your child will receive the study medication, STX209, for up to 8 weeks. The medication will then be gradually withdrawn over a 2-week period. Your child will be closely monitored for side effects and will be seen by a study doctor every 2 weeks.

The study medication and all study-related evaluations and are provided at no cost to you. The risks and benefits of this study will be explained to you thoroughly before you agree to participate.

If you are interested in participating, please contact Allison Gavaletz at (203) 785-6669 (email allison.gavaletz@yale.edu).

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

Sincerely,

Lawrence Scahill, MSN, PhD
Child Study Center, Yale University

IAN Ref: SR00201