

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: Seattle Children's Research Institute, 4800 Sand Point Way NE, Seattle, WA 98105

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: Bryan King, M.D.

Contact Information: Denise Unis, M.A., (206) 884-1168; denise.unis@seattlechildrens.org

Dear Parent,

I am writing this letter to let you know that your child has the option of participating in a research study at the Seattle Children's Research Institute. 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 several different psychological assessments to determine if STX209 has any effect on your child's symptoms. We are recruiting children with Autism or PDD-NOS who have emotional or behavioral difficulties such as moodiness, irritability, tantrums or aggression.

This is a 14-week research study. All patients will receive an investigational medication. All evaluations and medications for this study are provided without cost to participants. The risks and benefits of this study will be explained to you thoroughly.

There is no charge to participate in the study.

If you are interested in participating, please contact: Denise Unis, M.A., (206) 884-1168; denise.unis@seattlechildrens.org

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

Sincerely,

Bryan King, M.D.
Seattle Children's Hospital and Research Institute