

Name of Study: Neuronal Nicotinic Receptor Modulation in the Treatment of Autism: A Pilot Trial of Mecamylamine

Location: Nisonger Center at The Ohio State University, Columbus, Ohio

Eligibility Criteria: Children with Autistic Disorder or Pervasive Developmental Disorder Not Otherwise Specified, ages 4 through 12 years, in good physical health

Principal Investigator: L. Eugene Arnold, M.D., M.Ed.

Contact Information: Ashley Jones Reno, Research Coordinator; phone: (614) 688-8214; email: reno.37@osu.edu

Dear Parent,

This letter is to offer your child an opportunity to participate in a research study at The Ohio State University. This is a pilot trial studying whether the medicine called mecamylamine (Inversine) has an effect on the main core symptoms of autism (social impairment, communication impairment, and repetitive behaviors). Sixty percent of children will be assigned by chance to the active real drug and 40% to placebo (a fake pill). You and the doctor will not know which treatment your child receives the first 14 weeks.

The blinded part of the study lasts 14 weeks. After that there is an optional “open label” extension available, during which all children can receive the real medicine. This would be an additional 14 weeks.

Parents receive modest reimbursements for their time and travel costs, children will receive a small prize at each visit, and we take care of parking cost. All study medicine and evaluations are provided at no charge. It does not matter if the autistic disorder diagnosis is unknown or uncertain, as we must do a full research evaluation regardless. The results of evaluation and treatment can be sent to the doctor of your choice.

If you have questions or are interested in participating, please contact Ashley Reno, our study coordinator at (614) 688-8214 or email at reno.37@osu.edu to obtain further details without obligation.

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

Yours sincerely,

L. Eugene Arnold, M.D., M.Ed.

Professor Emeritus of Psychiatry

Interim Director, Nisonger Center of Excellence in Developmental Disabilities