

Study Title: Melatonin as Treatment for Sleep Disturbance in Autism Spectrum Disorders

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

Eligibility Criteria: Children with a diagnosis of Autism Spectrum Disorders, ages 5 to 12 years with sleep onset insomnia

Principal Investigator: Michael G. Aman, Ph.D.; phone: (614) 688-4196; email: aman.1@osu.edu

Contact Information: Jill Hollway; phone: (614) 247-6402; email: jill.hollway@osumc.edu

Dear Parent,

I write to inform you of a research study at The Ohio State University's Nisonger Center. The purpose is to test the effectiveness of melatonin in children and adolescents who have been diagnosed with Autistic Disorder, Pervasive Developmental Disorder-Not Otherwise Specified (PDD-NOS), or Asperger's Syndrome and have sleep disturbance.

This is a six-week study of the supplement melatonin which will be given to all participants. Participants will come to the Center a total of five times and a variety of assessments will be done. Parents will be asked to keep a sleep diary of their child's sleep habits as well as collect a urine sample at the beginning and end points of the study. To be eligible for this study, the patient must:

- Have a diagnosis of Autistic Disorder, PDD-NOS, or Asperger's Syndrome
- Sleep disturbance (trouble falling asleep or staying asleep)
- Age 5 to 12 years old, inclusive
- In good physical health

If the child has not been previously diagnosed as having an Autism Spectrum Disorder, a study psychiatrist will conduct diagnostic tests to confirm the diagnosis. We will summarize our findings for all families involved and send a copy to any clinician authorized by the parent.

If you have any questions, or if someone you know is interested in participating, please call Jill Hollway at (614) 247-6402 for further information.

Yours sincerely,

Michael Aman, Ph.D.

Professor of Psychology and Psychiatry

IAN ref: SR00136