

Name of Study: Clinical and Immunological Investigations of Subtypes of Autism

Location: National Institute of Mental Health (NIMH), Bethesda, Maryland (**will fly in participants who reside east of the Mississippi**)

Eligibility Criteria: Children 1 through 4 years, meeting specific criteria for one of the following study groups: **Autism; Developmental Delay; Typically Developing Controls**

Principal Investigator: Sue Swedo, M.D.

Contact Information: (301) 435-7962 or NIMH-ASD@mail.nih.gov

Dear Parent,

We would like to inform you about an opportunity for you and your child to participate in a research study at the National Institute of Mental Health (NIMH) – part of the National Institutes of Health (NIH), Department of Health and Human Services, located in Bethesda, Maryland.

This study has several goals. One aim is to look at specific aspects of autism, such as regression (where skills are lost). We will explore whether there is a unique change in immune functioning related to children with this feature. Another aim is to serve as one of the sites that will pilot a larger natural history study, entitled autism Phenome Project. The goal is to further understand autism by identifying other subtypes.

We will look at several types of medical issues that may be related to autism, including immunologic problems. Children will be followed over the course of several years. We aim to capture medical problems that may be related to autism as they develop, and study outcomes in areas such as behavior and language, in order to explore known and new subtypes of autism.

There will be an initial “baseline” visit, which will include a medical and developmental history, physical examination, psychological, cognitive and medical tests to assess symptoms of autism or other developmental disorders, and photographs of the child's face. This will also include an overnight electroencephalogram (EEG), and magnetic resonance imaging (MRI) scan, and for some children in the autism group, a lumbar puncture. The MRI and lumbar puncture may be done under sedation.

Follow-up visits are scheduled at different intervals, depending on study group, age and aspect of the study the child is enrolled in. The visits include a short interview session with the child's caregiver and assessment of the child's development and behavior. Some of the assessment measures used during the baseline examination are repeated, including symptoms ratings, behavioral tests and a blood test. For some children, the final visit will include repeats of the medical procedures.

Parents will receive a summary of findings from testing. There is no charge for study-related evaluations. Travel assistance may be provided.

If you are interested in participating, please call (301) 435-7962 for more information.

Sincerely,

Susan E. Swedo, M.D.

Branch Chief

Pediatrics and Developmental Neuropsychiatry

National Institute of Mental Health (NIMH)

National Institutes of Health (NIH)

Bethesda, Maryland

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