

Autism Screening Investigational Pupil Device Study



Early detection of Autism Spectrum Disorder (ASD) can improve a child's long-term quality of life. Researchers at Schweitzer Engineering Laboratories are conducting a clinical trial to examine the safety and effectiveness of an investigational device for screening for ASD in routine healthcare.

What is the study about?

Georgina Lynch, PhD, Principal Scientist, Keith Gautreaux, MD, and Kathryn Hryniewicz, MD are seeking 330 children aged 2 through 4 years old and their parent/legal guardians to participate in developmental assessments. This study uses an investigational pupillometer device to measure how the pupil responds to light. We will compare these measurements to standard behavioral screening assessments. This is a two-part study. All enrolled children will attend Part One, and 30 children will be selected to participate in Part Two.

How can my child and I participate?

You and your child may be eligible to participate in the trial if your child is between two years old and four years, 11 months old.

You and your child may not be eligible to participate if your child has:

- Experienced head trauma resulting in the need for medical care at an urgent care clinic, an emergency room, or required hospitalization
- A vision or hearing loss that impacts daily life functioning that has not been corrected or aided
- Experienced a seizure in the previous six months before study participation
- Known exposure before birth or accidental exposure after birth to alcohol, non-prescribed drugs (not over the counter), or environmental toxins (e.g. lead poisoning, poisonous liquids or substances)

What will we be asked to do?

- We will measure how your child's pupils respond to light by shining a light in their eyes.
- We will measure your child's height, weight, and head circumference.
- We will ask you questions about your child's development.
- We will evaluate your child's speaking, communication, and play skills.
- We will ask you to participate in play-based testing with your child.
- It will typically take 2.5 hours scheduled over 2–5 separate visits for you and your child to participate in the study. If your child is diagnosed with ASD, a 30–60-minute visit is required to discuss appropriate referrals and next steps.

Compensation

Upon enrollment, you will be given a \$25 gift card. If you participate in Part Two, you will be given two additional \$25 gift cards.

How will this study help others?

This study may help doctors screen for ASD more effectively in the future. Your child's participation may contribute to research that could improve future approaches to autism screening and referral for developmental evaluation. This device has not yet been cleared by the FDA for safety and effectiveness.

Interested?

Contact clinical research coordinator, Alyssa Knight at: clinicaltrials@selinc.com or 509.334.8800



This study has been approved for human subject participation by the Washington State University Institutional Review Board, IRB Approved Protocol # 26-0339-1



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