

## Autism Research Program at KPNC

Our research focuses primarily on identifying genetic and environmental risk factors for ASD, and understanding patterns of detection, diagnosis, and utilization of health services for ASD.

<b>Title</b>	<b>Type</b>	<b>Status</b>	<b>Eligibility</b>
Autism Treatment Network(ATN)	Medical Care	Recruitment Closed	2-17 year olds evaluated at the KP San Jose ASD Center
California Autism Twins Study (CATS)	Causes/Risk Factors	Recruitment closed	
Childhood Autism Perinatal Study (CHAPS)	Causes/Risk Factors	Data analysis only	
Development of a Brief Screener for Research Diagnoses of ASD	Diagnosis/Detection	Recruiting	2-17 year olds evaluated at the KP San Jose ASD Center
Diverse Autism Registry for Effectiveness Studies	Diagnosis/Detection Medical Care	Phase I: Data analysis only	
Early Autism Risk Longitudinal Investigation (EARLI)	Causes/Risk Factors	Recruiting	Women <28 weeks pregnant who have a child with ASD
Early Markers for Autism	Causes/Risk Factors	Data analysis only	
Immune-Related Co-Morbidities in Autism Spectrum Disorders	Causes/Risk Factors	Data analysis only	
Monitoring of Early Childhood Autism	Diagnosis/Detection	Data analysis only	
Study to Explore Early Development (SEED)	Causes/Risk Factors	Recruiting	2-5 year olds born and currently residing in Alameda or Santa Clara counties
Autism Spectrum Disorders in Preterm Infants	Causes/Risk Factors	Data analysis only	

## Study Descriptions

### **Autism Treatment Network**

The Kaiser Permanente San Jose ASD Center is one of 15 treatment and medical centers in North America working together, through the *Autism Treatment Network (ATN)*, to improve medical care for children and adolescents with autism. The goal of the ATN is to establish standards of clinical care for medical co-morbidities based on research and shared clinical experience. All ATN centers offer care from doctors highly experienced in treating patients with autism and dedicated to sharing their knowledge with the medical community. Doctors use a common protocol to conduct comprehensive evaluations of children with autism, and an anonymous database with participant clinical information provides essential data for research that evaluates and tracks patient care. This information is then used to develop protocols and standards. At the San Jose ASD Center, a total of 200 pediatric patients diagnosed with an ASD were enrolled in this study.

*Funders:* Autism Speaks, HRSA

*Site Principal Investigators:* Lisa Croen, PhD; Pilar Bernal, MD

### **California Autism Twins Study**

The *California Autism Twins Study (CATS)* is a collaborative study with Stanford University that seeks to determine causes and risk factors of ASDs. For this study, we are enrolling families with twins throughout California to learn whether some of the characteristics of autism, including impairments in social interaction, language, and learning, are shared between twins. We hope this information will help determine which characteristics of ASDs are more influenced by genetics and which are more influenced by other factors.

*Funder:* National Institute of Mental Health (NIMH)

*Collaborators:* Stanford University (lead); Kaiser Permanente Division of Research; University of California, San Francisco; Autism Genetic Resource Exchange (AGRE); the Medical Investigation of Neurodevelopmental disorders Institute (MIND); and the California Department of Public Health.

*Principal Investigator:* Joachim Hallmayer, MD, Stanford University

*Site Principal Investigator:* Lisa Croen, PhD

### **Childhood Autism Perinatal Study**

The *Childhood Autism Perinatal Study (CHAPS)* is a case-control study investigating whether there are factors before pregnancy, during pregnancy, or soon after birth that increase the risk of autism. For this study, investigators are reviewing and analyzing electronic medical record data from 2,520 children born at Kaiser Permanente hospitals between 1995 and 1999 and their mothers. Several prenatal, perinatal and neonatal factors are being evaluated, including maternal illnesses and medication use during pregnancy, complications during pregnancy, and infant characteristics.

*Funder:* The Centers for Disease Control and Prevention, Kaiser Permanente Community Benefit, and Autism Speaks

*Collaborators:* Kaiser Permanente Division of Research; California Department of Public Health

*Principal Investigator:* Lisa Croen, PhD

### **Development of a Brief Screener for Research Diagnoses of ASD**

The *Development of a Brief Screener for Research Diagnoses of ASD* is collaboration between Kaiser Permanente's Division of Research, the University of Michigan, and Cincinnati Children's Hospital Medical Center. The study aims to create a short screening questionnaire for research

that will identify children who are likely to have an ASD. Because this instrument will be brief, based on parent report, and appropriate for screening children ages 2 to 18, it will facilitate participant recruitment for future ASD studies. A version of the research instrument, called the ADI-Q, is currently being piloted with parents of children who have been referred to the San Jose ASD Center.

*Funder:* National Institute of Mental Health (NIMH)

*Collaborators:* Kaiser Permanente Division of Research; University of Michigan, Cincinnati Children's Hospital Medical Center.

*Principal Investigator:* Catherine Lord, PhD, University of Michigan

*Site Principal Investigator:* Lisa Croen, PhD

### **Diverse Autism Registry for Effectiveness Studies**

*A Diverse Autism Registry for Effectiveness Studies* is a research study that is part of the Mental Health Research Network. The goal of the study is to create a large, comprehensive and dynamic autism spectrum disorder (ASD) registry across several integrated health systems. The first phase of the study will look at variability across the participating health plans in the prevalence of ASD, in medical and psychiatric co-morbidities in the ASD population, and in the use of psychotropic medications to treat children and adolescents with ASDs. The second phase will look at different treatment approaches, and treatment burdens for families of children with ASD, and parental perceptions of the efficacy of different treatments. During the second phase of the study, parents of children diagnosed with an ASD who are Kaiser Permanente members will be invited to complete a Web survey and contribute a blood or saliva sample for future ASD research.

*Funder:* National Institute of Mental Health

*Collaborators:* Kaiser Permanente Northern California (Division of Research), Kaiser Permanente Southern California (Dept. of Research and Evaluation), Kaiser Permanente Northwest (Center for Health Research, Northwest), Kaiser Permanente Georgia (Center for Health Research, Southeast), and Harvard Pilgrim Health Care.

*Principal Investigator:* Lisa Croen, PhD

### **Early Autism Risk Longitudinal Investigation Study**

The *Early Autism Risk Longitudinal Investigation (EARLI)* study is a large multi-center study that seeks to identify causes and risk factors for ASDs. The study is enrolling a group of mothers of children with an autism spectrum disorder at the start of another pregnancy. The goal is to collect data on 1,000 mothers throughout their pregnancy and on the newborns through three years of age. Researchers will examine environmental exposures, genetic factors, and biological markers present during pregnancy and early life that may play a role in the development of ASDs.

*Funder:* National Institutes of Health (NIH), Autism Speaks

*Collaborators:* Drexel University; Kaiser Permanente Division of Research; Johns Hopkins University/Kennedy Krieger Institute; and University of California at Davis/MIND Institute.

*Network Principal Investigator:* Craig Newschaffer, PhD, Drexel University

*Site Principal Investigator:* Lisa Croen, PhD

### **Early Markers for Autism**

The goal of the *Early Markers for Autism (EMA)* study is to identify biologic factors that can be used to predict which children will have an ASD. Researchers are analyzing maternal blood collected during mid-pregnancy and infant blood collected at birth from children with ASD, children with mental retardation, and typically developing children. Investigators are examining a wide range of factors, including genetic factors, immune system factors, hormone levels, and environmental exposures.

*Funder:* National Institute of Mental Health (NIMH), National Institute of Environmental Health Sciences (NIEHS), National Alliance for Autism Research (NAAR), Autism Speaks  
*Collaborators:* Kaiser Permanente Division of Research; the California Department of Public Health; the Centers for Disease Control and Prevention (CDC); and scientists at UC Davis, UCSF, Utah State University, and Johns Hopkins University.  
*Principal Investigator:* Lisa Croen, PhD

### **Immune-Related Co-Morbidities in Autism Spectrum Disorders**

The major goal of the *Immune-Related Co-Morbidities in Autism Spectrum Disorders* study is to learn how often immune-related conditions, such as asthma, allergy, and autoimmune disease, occur in children with autism.

*Funder:* Kaiser Permanente Community Benefits Program  
*Principal Investigator:* Lisa Croen, PhD

### **Monitoring of Early Childhood Autism**

The *Monitoring of Early Childhood Autism (MECA)* project is a collaborative surveillance program to determine the prevalence of autism spectrum disorders (ASDs) in children less than 4 years of age. The study also aims to improve early identification of ASDs and provide useful data for planning ASD services. The MECA project also provides a unique opportunity to collaborate with community partners in Santa Clara County to conduct autism screening and surveillance among very young children.

*Funder:* Centers for Disease Control (CDC)  
*Collaborators:* Kaiser Permanente Division of Research; California Department of Public Health (CDPH)  
*Principal investigator:* Gayle Windham, PhD, CDPH  
*Site Principal Investigator:* Lisa Croen, PhD

### **Study to Explore Early Development**

The *Study to Explore Early Development (SEED)* is a national study investigating the genetic and environmental factors that might put children at risk for autism spectrum disorders (ASDs) and other developmental disabilities. Approximately 2,700 children between the ages of 2 and 5, and their families, are being invited to participate in research at six locations across the country including California, Colorado, Georgia, Maryland, North Carolina, and Pennsylvania. In California, SEED is being carried out in Alameda and Santa Clara Counties by Kaiser Permanente Northern California (KPNC) and the California Department of Public Health. The study is open to both Kaiser Permanente members and non-members who live in the area.

*Funder:* Centers for Disease Control and Prevention (CDC)  
*Collaborators:* Kaiser Permanente Division of Research; Colorado Department of Public Health and Environment; Johns Hopkins University in Maryland; University of North Carolina at Chapel Hill; and the University of Pennsylvania. The CDC is also participating in the study, and will include children and their parents from the metropolitan Atlanta area.  
*Site Principal Investigator:* Lisa Croen, PhD

### **Autism Spectrum Disorders in Preterm Infants**

The goals of the *Autism Spectrum Disorders in Preterm Infants* study are to investigate the incidence of ASD by gestational age in infants born prematurely, compare the incidence of ASD in premature infants to the incidence in term infants, and identify risk factors for the development of ASD in premature infants.

*Funder:* Kaiser Permanente Community Benefits Program  
*Principal Investigator:* Michael Kuzniewicz, MD, MPH, Kaiser Permanente Division of Research