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***NIH Autism Center of Excellence Network Announces Launch of
Most Comprehensive Study of Earliest Possible Causes of Autism***

Leading Researchers Nationwide to Participate in EARLI Study

(Philadelphia) – A network of leading autism researchers from three regions across the country today launched one of the largest research studies of its kind to investigate early risk factors for Autism Spectrum Disorders (ASD). The network, called the Early Autism Risk Longitudinal Investigation (EARLI), will follow a cohort of up to 1,200 pregnant women who already have a child with autism. The study is considered one of the best-equipped to discover biological markers and environmental risk factors for autism due to its elevated autism risk pregnancy cohort, wide ranging data collection with extensive bio-sampling, length of time it follows pregnant women and their babies, and multi-disciplinary team of expert investigators.

Under the study, researchers at four network field sites in three regions across the nation will study possible environmental risk factors and their interplay with genetic susceptibility during the prenatal, neonatal and early postnatal periods. The project will also investigate early biological indicators of autism. The EARLI Study is one of eleven National Institutes of Health Autism Centers of Excellence projects nationwide.

The Drexel University School of Public Health in Philadelphia is the national coordinator of the EARLI Study network. The local research sites for the study include: Drexel University School of Public Health/Children's Hospital of Philadelphia (CHOP); University of California at Davis/MIND Institute; Johns Hopkins Bloomberg School of Public Health/Kennedy Krieger Institute; and the Kaiser Permanente Division of Research in Oakland, CA.

“No other study can more comprehensively explore the impacts and interplay of environmental factors and genetic predisposition in the cause of autism,” said Dr. Craig Newschaffer, a department chair at the Drexel University School of Public Health and EARLI Study principal investigator. “Our approach is based on assessing potential autism risk factors through all-inclusive data collection that begins when a mother of a child with autism learns she is pregnant and continues through the early life of the new baby.”

The researchers aim to follow about 1,200 mothers of children with autism as soon as they become pregnant and document the development of the newborn through 36 months of age. “We also really need to involve families of children with autism in the study areas who may become pregnant in the future,” said Newschaffer. “If EARLI can stay in contact with large numbers of these families it will increase our chances of being able to follow mothers as soon as they become pregnant.”

According to EARLI researchers in the study, the study’s cohort of elevated autism risk pregnancies will help to greatly advance the understanding of possible autism environmental risk factors and biomarkers during different developmental windows, as well as the interplay of genetic susceptibility and environmental exposure. “The cohort will be one of the largest of its kind in the nation. By studying families who are already affected by autism, we feel we have the best chance at learning how genetics and environmental factors could work together to cause autism,” said Newschaffer. “The EARLI Study is expected to advance researchers’ understanding of the natural history and progression of ASD.”

“This study has unprecedented potential to help answer many of the questions families affected by autism face everyday, including questions about the genetic and environmental factors that contribute to autism” said Linda Birnbaum, Ph.D., National Institute of Environmental Health Sciences director. “The EARLI Study is a very comprehensive investigation that is geared towards identifying early signs of autism and understanding its earliest possible causes.”

The network also includes a data coordinating center at the University of California at Davis and a central lab and secure bio-sample repository at the Johns Hopkins Bloomberg School of Public Health.

Participants in the study will be followed for a period of up to four years, including the time during pregnancy and up until the newborn baby is three years old. The baby born during the study period will have a number of developmental assessments beginning at six months until three years of age. The older sibling with autism may also have additional assessments to confirm their diagnosis.

Mothers in the EARLI Study will be asked to fill out questionnaires, participate in phone interviews and provide biological samples. Researchers will also collect bio-samples of the newborn from birth through two years of age. The study participants will be compensated for their time as well as reimbursed for travel related expenses for visits to the clinic and will receive reports on the developmental assessments completed on their new babies.

Preliminary analyses are slated to begin as soon as the third year of enrollment. Analyses of the influence of genetic factors on developmental trajectory in high risk siblings are anticipated to begin after four years of EARLI Study enrollment. Other major analyses, including those involving interaction of genes and environment, will follow as more families complete the study protocol.

The EARLI Study was established with a \$14 million Autism Centers of Excellence grant awarded by the National Institute of Environmental Health Sciences, National Institute of Mental Health, *Eunice Kennedy Shriver* National Institute of Child Health and Human Development and National Institute of Neurological Disorders and Stroke, all components of the National Institutes of Health, to the Drexel University School of Public Health.

The EARLI Study is also supported by a \$2.5 million grant from Autism Speaks. The funding, made possible by an anonymous donation to Autism Speaks, expanded and linked two complementary multi-site, network studies that are both NIH Autism Centers of Excellence. The funding represented one of the largest public-private partnerships focused on understanding the causes of autism.

“Autism Speaks is pleased to provide additional support for this ground-breaking study. It is critical that we broadly explore early environmental and genetic risk factors for autism. Our hope is that the results of this study will someday allow us to identify infants at risk for the disorder and lead to better methods of treatment and prevention,” remarked Geri Dawson, Ph.D., Chief Science Officer at Autism Speaks.

ASDs refer to a group of complex neurobiological disorders that today are diagnosed in 1:150 US children. Boys are four times more likely to have an ASD than girls. ASDs are characterized by an impaired ability to relate to others and difficulties with verbal and nonverbal communication. Persons with ASDs also typically have repetitive behaviors, restricted interests, and/or tend to follow rigid routines. Although the degree of impairment across individuals with ASDs can vary, ASD is considered a serious developmental disability.

The causes of autism are unknown and there is currently no cure. The prevalence of autism has increased tenfold in the last decade. The Centers for Disease Control and Prevention consider autism to be a national public health crisis.

For more information about the EARLI Study, please visit <http://earlistudy.org>.

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ABOUT EARLI STUDY PARTICIPATING ORGANIZATIONS

Drexel University School of Public Health

The Drexel University School of Public Health promotes the health of communities through education, research, service and practice. As the *only* school of public health in Greater Philadelphia, Drexel’s innovative academic and research programs integrate real-world experience with classroom learning in one of the most diverse and culturally rich communities in the United States. Drexel’s School of Public Health is built on a foundation of understanding that health and human rights are inextricably entwined. This unique, community-collaborative approach fosters leadership and provides students with

the critically necessary hands-on experience to meet today's public health demands. For more information about the School of Public Health visit <http://publichealth.drexel.edu>.

Johns Hopkins Bloomberg School of Public Health

As a leading international authority on public health, the Johns Hopkins Bloomberg school of Public Health is dedicated to protecting health and saving lives. Every day, the School works to keep millions around the world safe from illness and injury by pioneering new research, deploying its knowledge and expertise in the field, and educating tomorrow's scientists and practitioners in the global defense of human life.

Kaiser Permanente Division of Research

The Kaiser Permanente Division of Research conducts, publishes, and disseminates epidemiologic and health services research to improve the health and medical care of Kaiser Permanente members and the society at large. It seeks to understand the determinants of illness and well-being and to improve the quality and cost-effectiveness of health care. Currently, DOR's 400-plus staff is working on more than 250 epidemiological and health services research projects. For more information visit www.dor.kaiser.org.

University of California at Davis M.I.N.D Institute

The UC Davis M.I.N.D. Institute (Medical Investigation of Neurodevelopmental Disorders) is an unique, collaborative center devoted to finding improved treatments, causes and eventually cures for autism, fragile X syndrome, Tourette syndrome, learning disabilities and other neurodevelopmental disorders. The Institute was founded in 1998 by dedicated families concerned about autism. Since that time, collaborative research teams at the M.I.N.D. Institute have turned that initial inspiration into significant contributions to the science of autism, fragile X syndrome, Tourette syndrome, learning disabilities and other neurodevelopmental disorders that can limit a child's lifelong potential. The community can help speed that process by enrolling their children in research studies. For more information about M.I.N.D. Institute research studies currently enrolling participants, visit <http://www.ucdmc.ucdavis.edu/mindinstitute/>.

Kennedy Krieger Institute

Internationally recognized for improving the lives of children and adolescents with autism and other developmental disabilities, the Kennedy Krieger Institute in Baltimore, MD serves more than 13,000 individuals each year through inpatient and outpatient clinics, home and community services and school-based programs. Kennedy Krieger provides a wide range of services for children with developmental concerns mild to severe, and is home to a team of investigators who are contributing to the understanding of how disorders develop while pioneering new interventions and earlier diagnosis. For more information on Kennedy Krieger Institute, visit www.kennedykrieger.org.

The Center for Autism Research

The Center for Autism Research (CAR) is a collaborative effort between The Children's Hospital of Philadelphia and the University of Pennsylvania. CAR's goals are to identify the causes of autism spectrum disorders (ASD) and develop effective treatments. CAR

conducts research studies for infants at risk for being diagnosed with ASD (due to having a sibling already diagnosed) as well as toddlers, school-aged children, and adults. Families receive comprehensive assessment reports and are paid for their time and travel costs. For more information, visit <http://stokes.chop.edu/car>.

National Institute of Environmental Health Sciences

The National Institute of Environmental Health Sciences (NIEHS) conducts research to reduce the burden of human illness and disability by understanding how the environment influences the development and progression of human disease. Please visit our website at <http://www.niehs.nih.gov>. The NIEHS is a component of the National Institutes of Health (NIH) within the U. S. Department of Health and Human Services. The NIH is the primary federal agency for conducting and supporting basic, clinical, and translational medical research, and it investigates the causes, treatments, and cures for both common and rare diseases. For more information about NIH and its programs, visit <http://www.nih.gov/>.

Autism Speaks

Autism Speaks is the nation's largest autism science and advocacy organization, dedicated to funding research into the causes, prevention, treatments and a cure for autism; increasing awareness of autism spectrum disorders; and advocating for the needs of individuals with autism and their families. Autism Speaks funds more than \$30 million each year in new autism research, in addition to supporting the Autism Treatment Network, Autism Genetic Resource Exchange, Autism Clinical Trials Network, Autism Tissue Program and a range of other scientific and medical programs. Notable awareness initiatives include the establishment of the annual United Nations-sanctioned World Autism Awareness Day on April 2 and an award-winning, multi-year national public service advertising campaign with the Ad Council. Autism Speaks' family services efforts include the Autism Video Glossary, a 100 Day Kit for newly-diagnosed families, a School Community Tool Kit and the distribution of community grants to local service providers. Its government relations department, through its Autism Votes initiative, has played a critical role in securing federal legislation to advance the federal government's response to autism, and has successfully advocated for insurance reform to require insurers to cover medically-necessary autism therapies. Each year, Autism Speaks *Walk Now for Autism* fundraising events are held in more than 70 cities across the country, as well as Canada and the United Kingdom.