



FNIH Supports New NIH Study Seeking Biomarkers for Autism Spectrum Disorders

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The Foundation for the National Institutes of Health (FNIH) announced today a public-private collaboration with the National Institute of Mental Health (NIMH), a component of the National Institutes of Health, and the Simons Foundation Autism Research Initiative (SFARI), among others. The four-year partnership will help fund a study of preschool (3-5 years) and school-aged (6-11 years) children with Autism Spectrum Disorders (ASD) to identify non-invasive biological markers (biomarkers) that could help physicians diagnose the condition, track progression and assess the effectiveness of treatment. Supported by a \$2 million grant from SFARI and managed under the FNIH Biomarkers Consortium (www.biomarkersconsortium.org), this project brings funds and expertise to a \$28 million initiative of the NIH. In addition to support from the NIMH, the NIH award is co-funded by the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development and the National Institute of Neurological Disorders and Stroke.

The study, which is led by a team of researchers from Yale School of Medicine, will collect data from children over a 24-week period and evaluate key facets of social-communication in ASD using a number of measures—assessments of social impairment, such as clinician, caregiver and lab-based tools, as well as neurophysiological measures, such as eye tracking and electrophysiological (EEG). Researchers will also collect blood (DNA) samples from ASD subjects, including parents of ASD subjects, for future genomic analyses. Data collection will take place across five sites: Duke University, Boston Children’s Hospital, University of California at Los Angeles, University of Washington/Seattle Children’s Research Institute and Yale School of Medicine.

ASD affects early brain development and can present signs and symptoms within the first two years of life. It is estimated that ASD affects 1 percent of children worldwide. A lack of defined measures of change in social functioning makes it difficult for researchers to develop interventions for the core social impairment of autism. The ultimate goal of this study is to produce a set of measures that can be used as biomarkers of social impairment in ASD and that could serve as indicators of long term clinical outcome in clinical and drug development studies.

“Early diagnosis and intervention can improve the outcomes of children with ASD. Validating predictive biomarkers is critical to providing earlier detection and better interventions,” said NIMH Director Thomas R. Insel, M.D.

In addition to funding from SFARI, the FNIH Project Team for the ASD Biomarkers Project will receive in-kind support in the form of technical input and expert advice from Janssen Research and Development, LLC and the European Autism Interventions-A Multicentre Study for Developing New Medications (EU-AIMS) throughout the duration of the project. The Foundation will work closely with multiple partners and stakeholders—including SFARI, the U.S. Food and Drug Administration, Janssen Research and Development, LLC, and EU-AIMS—to provide critical input and coordination among the public and private sector partners for this effort.

“Large-scale collaborations between public and private stakeholders are needed to address key barriers to developing new treatments for ASD,” said FNIH President and Executive Director, Maria C. Freire, Ph.D. “This partnership represents the first of what will hopefully be many successful collaborations of this type.”

"SFARI is committed not only to understanding the science underlying autism spectrum disorders but also to identifying ways in which we can improve the lives of those on the autism spectrum," said SFARI Director of Clinical Research Wendy Chung, M.D., Ph.D. “Identification of biomarkers and early diagnosis is a big part of that, and robust study of this population is key to making that possible.”

For more information about the study, please visit www.nimh.nih.gov.

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About the Foundation for the NIH

The Foundation for the National Institutes of Health creates and manages alliances with public and private institutions in support of the mission of the NIH, the world’s premier medical research agency. The Foundation, also known as the FNIH, works with its partners to accelerate key issues of scientific study and strategies against diseases and health concerns in the United States and across the globe. The FNIH organizes and administers research projects; supports education and training of new researchers; organizes educational events and symposia; and administers a series of funds supporting a wide range of health issues. Established by Congress in 1996, the FNIH is a not-for-profit 501(c)(3) charitable organization. For additional information about the FNIH, please visit www.fnih.org.