

Public release date: 7-Sep-2006

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Contact: Karin Lee
NIMHpress@nih.gov
301-443-4356

[NIH/National Institute of Mental Health](#)

New National Institute of Mental Health research program launches autism trials

The National Institute of Mental Health (NIMH), part of the National Institutes of Health (NIH), has launched three major clinical studies on autism at its research program on the NIH campus in Bethesda, Maryland. These studies are the first products of a new, integrated focus on autism generated in response to reported increases in autism prevalence and valid opportunities for progress. Initial studies will define the characteristics of different subtypes of autism spectrum disorders (ASD) and explore possible new treatments.

One study will define differences--both biological and behavioral--in autistic children with diverse developmental histories. Increasingly, scientists are considering the likelihood of "autisms," that is, multiple disorders that comprise autism. These studies seek to better define the subtypes within autism. Children with regressive autism appear to develop normal language and social skills but then lose these with the onset of autism before age 3. Non-regressive autism, the more common form of the disorder, begins early in life, possibly before birth, with evidence of subtle deficits throughout development. Children with these two forms of autism will be compared with those who have other developmental disorders, including various forms of developmental delay, as well as children with typical development. In addition, researchers will study a subset of the children in this study to investigate environmental factors that may trigger symptoms of autism.

In another study, NIMH researchers will examine the use of the antibiotic minocycline to measure its usefulness in treating regressive autism. Past research suggests that autism may be linked with changes in the immune response that cause inflammation in the brain. Minocycline has known anti-inflammatory effects and has been shown to be helpful in other brain disorders such as Huntington's disease.

The third study seeks to address the widespread but unproven theory that autism may be treated successfully by chelation therapy, which seeks to remove heavy metals from the blood. Chelation is more commonly used to treat lead toxicity, but currently, many families seek the treatment to try to remove mercury and other metals from their autistic children's blood. This practice is based on the belief that many cases of autism were caused by exposure to thimerosal, a mercury-based preservative previously used in childhood vaccines.

According to the Food and Drug Administration, since 2001, all vaccines recommended for children 6 years of age and younger have contained either no thimerosal or only trace amounts, with the exception of inactivated flu vaccine, which is manufactured in formulations both containing and free of thimerosal. Thimerosal-free influenza vaccine licensed for use in children six to 23 months of age is available in limited supply. Additionally, new pediatric vaccines that have received licensure do not contain thimerosal.

Regardless, many families continue to turn to chelation as a therapy for autism. NIMH will conduct a controlled study to test the efficacy and safety of chelation for children with autism spectrum disorders. However, the chelation also can remove essential mineral nutrients, such as calcium, iron, and zinc.

"Because chelation therapy is not specific for mercury alone, it is important to conduct a systematic, controlled trial to determine whether or not chelation therapy is beneficial or potentially harmful to children with autism," says Susan Swedo, M.D., who leads the branch on pediatric behavioral research in the NIMH Division of Intramural Research Programs, where the autism studies are being conducted.

Autism is a mental disorder that arises in early childhood and is characterized by delays in development of social and communication skills, as well as restricted interests and repetitive behaviors. Autism has a variety of presentations, and may represent several different diseases. It is part of a larger group of disorders, often referred to as autism spectrum disorders or ASDs, that also includes Asperger's syndrome and pervasive developmental disorder. Developing better screening or diagnostic tools and finding effective treatments depend on gaining more information about these various disorders and subtypes, which currently are reported to affect 2-6 out of every 1000 children.

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The NIMH Intramural Research Program is committed to conducting reliable and unbiased clinical research to improve human health. Each of the proposed studies has undergone a rigorous review process to ensure the quality and safety of the research. To learn more about this process or to find general information on clinical trials, please visit <http://ClinicalTrials.gov>.

Approximately 500 scientists work in the NIMH Division of Intramural Research Programs located on the main NIH campus in Bethesda, Maryland. Intramural scientists range from molecular biologists working in laboratories to clinical researchers working with patients at the NIH Clinical Center. Through its Division of Extramural Activities, NIMH supports more than 3,500 research grants and contracts to researchers at universities and other institutions across the country and overseas. On average, over 80 percent of the NIMH research budget is allotted to extramural research. To learn more about the different research divisions at NIMH, please visit <http://www.nimh.nih.gov/about/compon.cfm>.

The National Institutes of Health (NIH) -- The Nation's Medical Research Agency -- includes 27 Institutes and Centers and is a component of the U.S. Department of Health and Human Services. It 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 www.nih.gov.

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