

Press Release

For Immediate Release:
June, 2010

Contact: Walter Zahorodny, PhD
New Jersey Medical School

Researchers at NJ Medical School Receive CDC Autism Grant

UMDNJ-New Jersey Medical School was awarded \$1,700,000 by the Centers for Disease Control and Prevention (CDC) to continue identifying and evaluating changes in the number of children with autism spectrum disorders (ASD) and other developmental disabilities in New Jersey.

CDC has awarded a total \$5 million per year to 11 sites in Alabama, Arizona, Arkansas, Colorado, Maryland, New Jersey, Missouri, North Carolina, South Carolina, Utah and Wisconsin. These sites participate in the Autism and Developmental Disabilities Monitoring (ADDM) Network to provide comparable, population-based estimates of the number of 8-year-old children with ASD and other developmental disabilities in different US locations, over time.

“Over the last decade, we've learned that autism affects about one out of every 110 American children,” said Kathleen Sebelius, secretary of Health and Human Services. “The collaboration with these grantees is one part of an historic new investment in autism research by our agency and others to better understand this urgent public health challenge and address the complex needs of people with autism and their families.”

“These grantees are vital to CDC’s commitment to improve the identification of children with autism spectrum disorders in different areas of the country and among different groups of children.” said Dr. Edwin Trevathan, director of CDC’s National Center on Birth Defects and Developmental Disabilities. “The information each site collects helps estimate the number of children affected by autism spectrum disorders, facilitates learning about the characteristics of children with autism spectrum disorders, and assists communities in planning for services.”

ASD are a group of developmental disabilities that can cause significant challenges in social interactions and communication. Children with ASD handle information in their brain differently than other people, and might have unusual ways of learning, paying attention, and reacting to different sensations. ASDs are part of the broader category of pervasive developmental disorders and include autistic disorder, Asperger disorder, and pervasive developmental disorder-not otherwise specified. For information on CDC's work on autism, please visit www.cdc.gov/autism.

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New Jersey Autism Study

New Jersey Medical School – University of Medicine and Dentistry of New Jersey

New Jersey and many states have seen increases in the number of children diagnosed with autism. Until recently, however, the true prevalence of autism in New Jersey was undetermined and it was not possible to know whether the apparent increase in autism was due to better recognition of the disorder or to an actual increase in prevalence.

The **New Jersey Autism Study** was established by researchers at the New Jersey Medical School, in cooperation with the New Jersey Department of Education and the New Jersey Department of Health and Senior Services. The aims of the **New Jersey Autism Study** are to provide the most accurate, population-based, information regarding the occurrence and expression of autism, to monitor changes in autism prevalence in our state, over time, and to identify possible risk factors for autism and disparities in the identification and treatment of autism.

The ascertainment method used by the **New Jersey Autism Study** was developed by the Centers for Disease Control and Prevention (CDC) and involves a two-phase process involving systematic review of existing health and education records, followed by independent case-determination and analysis by experts, using DSM-IV-based diagnostic criteria.

Given the thoroughness of the case-finding method and the size of the New Jersey population, the **New Jersey Autism Study** is implemented in four counties (Hudson, Essex, Union and Ocean) and restricted to 8-year old children born in specific years. The four surveyed counties are populous and diverse, encompassing 25% of the total state population.

The first subjects of this investigation were cohorts of 8-year old children, born in 1992 and 1994. Baseline autism prevalence rates for the New Jersey surveillance region have been determined for two years – 2000 and 2002.

The **New Jersey Autism Study** has been supported by the CDC and the New Jersey Governor's Council for Medical Research and Treatment of Autism. For more information please visit: www.cdc.gov/autism and www.njautismcouncil.org.

The **New Jersey Autism Study** has identified a high rate of autism in the surveillance region. In 2000 and 2002, autism prevalence was **9.9 per 1,000** and **10.6 per 1,000**, respectively. These autism rates are significantly higher than estimates from earlier US population-based studies and higher than rates determined by the autism and Developmental Disabilities Monitoring (ADDM) Network – 14 US autism surveillance sites using common definitions, methods and procedures, for cohorts in the same time period.

A **1% prevalence rate** confirms that autism is one of the most common severe developmental disabilities. Since the four-county New Jersey surveillance area is demographically-consistent with the surrounding New York-New Jersey Metropolitan Region, estimates by the **New Jersey Autism Study** are likely to reflect autism prevalence throughout the entire region.

While we do not yet know why autism rates are higher in our region, the **New Jersey Autism Study** is currently investigating this question through a number of collaborative case-control studies. Most importantly, the **New Jersey Autism Study** is currently monitoring autism surveillance in our region for 2006 and 2008 and plans to maintain surveillance activities into the future, to determine any changes in the occurrence or expression of autism.

By appreciating the true scope of autism in our state and by researching autism trends, we can make realistic plans for serving affected children and their families, specify possible autism causes and risk factors and identify any disparities in the care of persons with this devastating disorder.

For further information, please contact:

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NOTICE OF APPROVAL OF CONTINUATION AND MODIFICATION

IRB PROTOCOL NUMBER: 0120010288
(Refer to this number when making inquiries)

PRINCIPAL INVESTIGATOR/DEPT: Walter Zahorodny Ph.D.
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CO-INVESTIGATOR(S): Franklin Desposito, M.D. Richard Goldsmith, M.D. Randy Huron, M.D. Uday Mehta, M.D. Pauline Thomas, M.D. Audrey Mars, M.D. Jan Wollack, M.D., Ph.D.

TITLE: New Jersey Autism Study

PERFORMANCE SITE(S): UMDNJ-University Hospital; Hackensack University Medical Center, Trinitas Hospital

SPONSOR/PROTOCOL NUMBER: Centers for Disease Control and Prevention (CDC)1UR3DD00077-01

STUDY STATUS: Enrolling/Treating Subjects

TYPE OF REVIEW: Expedited (9)

TYPE OF APPROVAL: RENEWAL

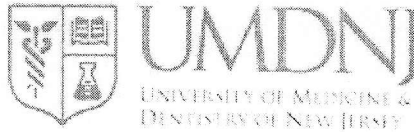
RISK DETERMINATION LEVEL: Minimal Risk

DEVICE DETERMINATION: Not Applicable

VULNERABLE POPULATION CODE(s): 45CFR46.404; No Pregnant Women as Subjects; No Prisoners As Subjects

APPROVAL DATE: 6/22/2009 **EFFECTIVE DATE:** 6/25/2009 **EXPIRATION DATE:** 6/21/2010

1. **Adverse Events:** Any on-site serious adverse events, or any unanticipated problems involving risk to subjects or others, or any serious or continuing non-compliance that occurs in relation to this study must be reported to the IRB Office (45 CFR 46, 21 CFR 50, 56) as outlined in the investigator instructions for adverse event reporting.
2. **Continuing Review:** Approval is valid until the protocol expiration date shown above. The IRB must review and approve all human subject research studies at intervals appropriate to the degree of risk, but not less than once per year, as required by 45 CFR 46 and 21 CFR 50, 56. In order to avoid lapses in approval of your research and the suspension of subject enrollment, please submit your continuation application at least eight weeks before the study expiration date.
3. **Consent:** Informed consent has been waived by the IRB in accordance with 45 CFR 46.116 and 45 CFR 164.512 (HIPAA) for this retrospective review of existing data collected from **January 1, 2006** to **December 31, 2006**.
4. The investigator(s) did not participate in the review, discussion, or vote of this protocol.
5. **Data Collection:** Number of charts approved at this site: **5,000**



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6. **Amendments/Modifications/Revisions:** If you wish to change any aspect of this study, including but not limited to study procedures, consent form(s), principal investigator, co-investigator(s), advertisements, the protocol document or procedures, the investigator drug brochure, or accrual goals, you are required to obtain IRB review and approval under 45 CFR 46 and 21 CFR 50, 56. Implementation of these changes may not occur until you receive notice of IRB review and approval.
7. **Completion of Study:** Please notify the IRB when your study has been stopped for any reason. Include the following information in the written notification using a continuing review/final report form: number of subjects enrolled; number of subjects withdrawn from the study; and reason for study termination. Neither study closure by the sponsor or the investigator removes the obligation for timely continuing review or a final report.
8. **Wards of the state:** Not applicable
9. **Modification:** Addition of Danielle Rosivack as research assistant to the protocol. Delection of Toralben Patel, MD as research assistant to the protocol. Centers for Disease Control funding will begin June, 1, 2009, taking the place of the previous sponsor, New Jersey Governor's Council on Autism.


Carlotta M. Rodriguez, B.S., C.I.P. - NWK IRB Director

Date: 6/26/09

CC: Department Chair

DHHS Federal Wide Assurance Identifier: **FWA00000036**

Regarding HIPAA:

HIPAA [45 CFR Parts 160 and 164]: Under this rule, covered entities may disclose, without individual authorization or consent, protected health information to public health authorities "...authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions...." The definition of a public health authority includes "...an individual or entity acting under a grant of authority from or contract with such public agency...." [45 CFR § 164.501]

2010 New Jersey Autism Study

Clinical Source Data Set Request

Please create a dataset representing every patient in your practice/program:

- **Born in 2002** (January 1, 2002-December 31, 2002)
- Residing in **Union, Essex, Hudson, Ocean counties anytime in 2010**
- With **ANY** pediatric developmental, neurological, or psychiatric **diagnosis**
(See attached ICD 9 Code List for all possible diagnostic codes)
- With **ANY** date of service in **2010 or before**

Please note your dataset will encompass children who were 8 years old in 2010.

Your dataset should include (patient) name, date of birth, sex, race, medical record number, home address, first and last dates of service (if available) and **ALL** ICD-9 codes. (Please see the attached Suggested Record Layout and the ICD-9 codes to be included in this study).

If your program codes race information, please provide the de-coding scheme.

If you can provide your dataset as an Excel file, that would be appreciated. A sample record layout for Excel is attached. We can accept your dataset in any format, including as a paper list.

When your dataset is ready, please call **973-972-6577**, to arrange receipt of your data set. Our staff will come to your program, in person, to receive the dataset or you will send the dataset by UPS Next Day secure delivery.

Please do not e-mail your data set.

Please contact the study investigator, Dr. Walter Zahorodny (973-972-6577; zahorodn@umdnj.edu), with any questions or comments.

Thank you.

SUGGESTED RECORD LAYOUT: CLINICAL SOURCES

NEW JERSEY AUTISM STUDY

CHILDREN BORN IN 2002

ANY DATE OF SERVICE IN 2010 OR BEFORE

RESIDENCE IN UNION, ESSEX, HUDSON OR OCEAN COUNTY

<u>FIELD</u>	<u>DESCRIPTION AND COMMENTS</u>
LAST NAME	Last name of child
FIRST NAME	First name of child
DATE OF BIRTH	Child's birth date
SEX	Child's sex
RACE	Child's race
MEDICAL RECORD NUMBER	Please provide, if available
DATES OF SERVICE	Please provide 1 st & last, if available
HOME ADDRESS	Street address where child resides
CITY	City or town where the child lives
ZIP	ZIP Code for town of residence
ALL ICD 9 CODES	Please list All ICD-9 codes

NJAS SAMPLE RECORD LAYOUT												
LAST NAME	FIRST NAME	DOB	SEX	RACE	MED REC #	FIRST DOS	LAST DOS	ADDRESS	CITY	ZIP	ICD 9	ICD 9
Smith	John	02/02/02	M	White	221234	10/2/2004	12/22/08	123 Main St	Westfield	07090	299	
Torres	Juan	12/25/02	M	Hisp.	9665	1/6/2002	5/7/08	2233 North Av	Union	07083	314	319