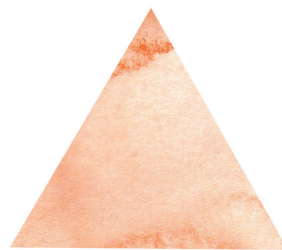
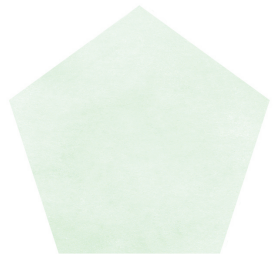
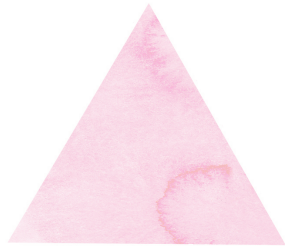
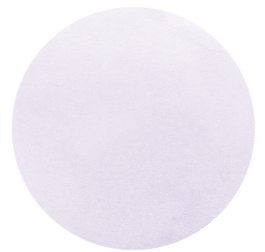
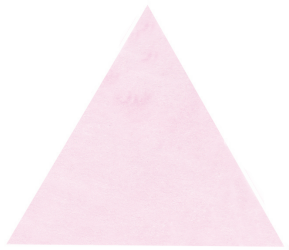


08

ASD Research Opportunities

POTENTIAL ADDITIONAL RESEARCH OPPORTUNITY





Research around the country on ASD has focused on identifying autism genes, such as the genome sequencing effort spearheaded by Autism Speaks; understanding the initial causes of autism and ways to prevent its manifestation; and in some cases, the effectiveness of treatment interventions, including nutritional and therapeutic.



Research related to clinical interventions for autism is extremely limited in the Capital Region. Several national funding opportunities exist but none of these programs have been pursued by any institution in Louisiana.



A trio of organizations in the Capital Region appear well-positioned to consider pursuit of research opportunities.



Pennington Biomedical Research Center (PBRC)

The Pennington Biomedical Research Center (PBRC) is located in Baton Rouge and is nationally recognized for its research in diabetes, obesity, and nutrition. The mission of PBRC is “to discover the triggers of chronic diseases through innovative research that improves human health and the lifespan.”

In 2005, Pennington Biomedical received a National Institutes of Health (NIH) grant to establish a Center of Excellence in Botanicals and Metabolic Syndrome. This center studies how plant extracts can treat Metabolic Syndrome and Type 2 Diabetes. Pennington Biomedical also received an NIH grant to establish an NIH-NIDDK¹⁹¹ Clinical Nutrition Research Unit to identify prenatal causes of obesity.

In 2006, the Pennington Biomedical Research Center’s Center of Biomedical Research Excellence (COBRE) was established with an award through the NIH to provide support for outstanding junior faculty as they transition from training to establishing their own research programs.

Throughout its history, Pennington has partnered with the U.S. Army, NASA, the Department of Defense, the State of Louisiana, the NIH, the NIDDK, and others to study the effects of diet, nutrition, and exercise on diabetes, obesity, and metabolic conditions. Although not directly related to autism spectrum disorders, the interaction between the brain and the gut are critical to understanding autism. PBRC has much of the infrastructure and scientists in place to phase the study of ASD into its work.

191 NIDDK – National Institute of Diabetes and Digestive and Kidney Diseases.



Irene W. and C.B. Pennington Foundation

The Irene W. and C.B. Pennington Foundation has pursued relationships with Sheppard Pratt and the Lieber Institute for Brain Development to “generate preliminary data about the biological associations of [the] variable outcomes” possible with an ASD diagnosis. This research is intended to serve as a “proof of concept for larger studies that can drive the development of effective intervention strategies.”¹⁹² The Lieber Institute will be taking a holistic approach to their research, looking at medical, dietary, environmental, educational, and other factors that impact differing outcomes for adults on the autism spectrum.

Our Lady of the Lake Regional Medical Center

Our Lady of the Lake Regional Medical Center broke ground on its free-standing Children’s Hospital in Baton Rouge in February of 2016. This new hospital will function as a regional pediatric services complex capable of attracting medical specialists and services not currently available or in critically short supply in the Capital Region. The new hospital could also catalyze a new level of collaboration among pediatric care providers and serve as a strategic partner that facilitates the establishment of ASD clinical research in the Capital Region.

Our Lady of the Lake Pediatric Development and Therapy Center

As discussed in the **Medical Comorbidities** section of this report, the services administered by this proposed Center will include neurology, genetics, developmental pediatrics, social services, speech pathology, occupational therapy, physical therapy, and psychological services. This facility will also integrate medical subspecialty services for related comorbid health conditions related to gastrointestinal function, pulmonary function, and sleep disorders in its treatment to provide a holistic approach to therapy. This center envisions becoming a hub of treatment and research related to ASD and other co-occurring medical conditions.

¹⁹² <http://www.prnewswire.com/news-releases/pennington-family-foundation-awards-200000-grant-to-lieber-institute-for-brain-development-for-autism-research-300089400.html>



Many local providers and universities work closely together to conduct research studies. Fostering the relationships between providers, universities, hospitals, and research facilities will provide for more robust research initiatives leading to quicker application and impact on the population.

Specific funding opportunities currently exist for research focused on ASD, including Autism Treatment Networks, Autism Centers of Excellence, Autism Intervention Research, Department of Defense Congressionally Directed Medical Research programs, and Autism and Developmental Disabilities Monitoring Networks. A summary description of each follows.

Autism Treatment Network

The Autism Treatment Network (ATN) is a national network of hospitals and physicians focused on improving the treatment of individuals with autism. Seventeen ATN sites have been approved by Autism Speaks with Houston and Little Rock being geographically the closest to Baton Rouge. ATNs are self-sufficient facilities that generate their own funding streams through treatment and research grants from the NIH primarily, but ATNs also are supported through Autism Speaks.

Funding as an ATN: approximately \$165,000 per year for three years

For more information on the Autism Treatment Network, visit <http://www.asatn.org/>.

Autism Centers of Excellence

Autism Centers of Excellence (ACE), funded by the NIH, bring together expertise, infrastructure, and resources focused on major questions about autism. ACEs are collaborations of basic and clinical scientists. The research objectives of these centers can include intervention projects, service projects, or other identified priority research objectives, for example: identification of biological signatures for autism and their relevance to prediction of treatment response and outcomes.

Funding as an ACE: \$1.5 million (annual)

Approximately ten to 15 ACE awards anticipated in each round.

For more information on ACE, visit <https://www.nichd.nih.gov/research/supported/Pages/ace.aspx>.



Autism Intervention Research

The Autism Intervention Research (AIR) network works in conjunction with ATNs but secures funding through the Health Resources and Services Administration (HRSA) and the federal Autism Cares Act – recently renewed for \$260 million annually over the next five years. This funding is designed to support clinical research on children with autism to develop a standard protocol for treatment. There are three programs funded through this grant: Autism Intervention Research Program (AIR-P), Secondary Data Analysis Studies (SDAS), and Autism Longitudinal Data Project (ALDP).

Autism Intervention Research Network on Physical Health

This program supports applied empirical research studies to advance the evidence base on the effectiveness of interventions to improve the health and well-being of children and adolescents with ASD and other developmental disabilities and to advance best practices for the diagnosis of ASD and other developmental disabilities at an earlier age.

Funding: approximately \$300,000 over three years per grantee

For more information on AIR-P, visit <http://www.airpnetwork.org/>.

Secondary Data Analysis Studies

This program supports secondary data analysis to advance the evidence base on the effectiveness of interventions and to advance best practices for the diagnosis of ASD and other developmental disabilities at an earlier age.

Funding: approximately \$100,000 for one year

Autism Longitudinal Data Project

This program supports the implementation and completion of research studies that examine longitudinal data on ASDs and other developmental disabilities to study risk factors of these conditions, the effects of various interventions, and trajectories of child development over the life course.

Funding: approximately \$500,000 per year for three years

Department of Defense (DoD) Congressionally Directed Medical Research Programs: Autism

This grant award program supports research with the potential to have a major impact on the treatment and management of ASD. Funding must support a clinical trial and may not be used for preclinical research studies. The FY2015 appropriation was \$6 million (total for both the clinical and idea development award). These awards are determined by a panel of consumers (people who both treat autism and are affected with a diagnosis).

Funding: approximately \$1 million over five years

For more information on DoD CDMRP, visit <http://cdmrp.army.mil/arp/>.

Autism and Developmental Disabilities Monitoring (ADDM) Network

This funding opportunity is intended to enhance the capacity of surveillance programs to implement or enhance a population-based, multiple-source surveillance program for ASD and other developmental disabilities that co-occur with ASD. The project will fund sites to participate in the network and will enhance surveillance activities through two components: (A) surveillance of eight-year-olds and (B) surveillance of four-year-olds. The eight-year-olds' surveillance is required and the four-year-olds' surveillance is optional.

Funding:

Component A: approximately \$450,000 for one year; Component B: approximately \$125,000 for one year.

ADDM works on a four-year grant cycle with the current cycle having begun in January 2015.

For more information on ADDM, visit <http://www.cdc.gov/ncbddd/autism/addm.html>.



POTENTIAL ADDITIONAL RESEARCH OPPORTUNITY

The 21st Century Cures Act passed by the United States House of Representatives would extend \$8.75 billion to the National Institutes of Health. Additionally, NIH would host a new Cures Innovation Fund specifically dedicated to breakthrough biomedical research. While not directly geared toward autism, this bill would impact funding and clinical trials through the NIH. This bill would “streamline various regulations and requirements to make sure researchers are able to comply with them, and it would eliminate duplication in the review process by fostering broader utilization of central institutional review boards (IRBs) for trials being conducted at multiple institutions.”¹⁹³ Earlier this year, the Senate signaled it would not take up the bill, although some Senate committees have passed bills that support the 21st Century Cures Act and provide additional funding for NIH.¹⁹⁴

As other recommendations from this report are implemented, the infrastructure and capacity for research will be greatly expanded. Provider organizations with an appropriate patient base for research could serve as research partners – especially research focused on best practices for treatment intervention.



¹⁹³ <http://energycommerce.house.gov/fact-sheet/hr-6-21st-century-cures-act-frequently-asked-questions>
¹⁹⁴ <https://ehrintelligence.com/news/help-committee-passes-bills-supporting-21st-century-cures-act>



08

RECOMMENDATION

ASD RESEARCH OPPORTUNITIES



The substantial health care delivery, education, and research infrastructure in the Capital Region offers great potential for participating in national ASD care and research initiatives.

1. Our Lady of the Lake Children's Hospital and the Pennington Biomedical Research Center should lead a sustained effort to establish the Capital Region as a Nationally Recognized ASD Research and Care Network Hub with a specific emphasis on biomedical treatments and therapies for those with ASD.

Through this effort, the Capital Region could create an Autism Treatment Network (ATN) facility as well as an Autism Center of Excellence that is eligible for federal funding. Achieving this status helps in the pursuit of additional federal dollars for research related to autism. Further, Baton Rouge should work to develop the necessary capacity and resources to become an Autism and Developmental Disabilities Monitoring Network site.

The Our Lady of the Lake Pediatric Development and Therapy Center, a neurodevelopmental therapy and autism treatment center, wants to become an Autism Treatment Network facility when fully implemented and should be a natural site for implementation.