

QUESTION 7: WHAT OTHER INFRASTRUCTURE AND SURVEILLANCE NEEDS MUST BE MET?		
IACC Strategic Plan Objectives	Planning Group Summary	Total Funding 2008-2012
<p>7A. Conduct a needs assessment to determine how to merge or link administrative and/or surveillance databases that allow for tracking the involvement of people living with ASD in health care, education, and social services by 2009.</p> <p><i>IACC Recommended Budget: \$520,000 over 1 year</i></p>	<p>Funding: The Planning Group is not aware of any efforts (projects or funding) that have been made to address this objective since it was created.</p> <p>Progress: No progress has been made on this objective.</p> <p>Remaining Gaps, Needs and Opportunities: A needs assessment remains necessary due to issues surrounding patient privacy in linked databases and to determine how this connection is possible with existing tools and resources. It remains to be decided whether this should be a government led effort or a public/private partnership. Such resources could be utilized by both the research and services provision community.</p>	\$0
<p>7B. Conduct an annual "State of the States" assessment of existing State programs and supports for people and families living with ASD by 2011.</p> <p><i>IACC Recommended Budget: \$300,000 each year (revised in 2010)</i></p>	<p>Funding: The recommended budget was partially met.</p> <p>Progress: Centers for Medicare & Medicaid Services (CMS) is working on this project and anticipates release of the report summarizing the results of the study in 2014. The book Autism Services Across America by Dr. Peter Doehring also reviews existing programs and services across the states.</p> <p>Remaining Gaps, Needs, and Opportunities: The initial State of the States study, overseen by CMS, will be completed and published by 2014, but the objective called for an annual study. Since the first study took multiple years and it is not clear if the services will change enough yearly to warrant an annual study, this objective should be revisited with CMS to understand whether an annual study is still needed or feasible.</p>	\$604,013
<p>7C. Develop and have available to the research community means by which to merge or link databases that allow for tracking the involvement of people in ASD research by 2010.</p> <p><i>IACC Recommended Budget: \$1,300,000 over 2 years</i></p>	<p>Funding: The recommended budget was met.</p> <p>Progress: The Interactive Autism Network (IAN) and Group Health Cooperative Autism Registry are two examples of projects that are responsive to this objective. This objective should be considered to be met, with funding exceeding the recommended budget and a large number of diverse projects addressing this issue. NDAR, IAN and AGRE are all publicly available.</p> <p>Remaining Gaps, Needs and Opportunities: To advance this objective we need to encourage patients and families to join the registry compared to registry numbers for cystic fibrosis (100%) Autism is behind at ~4% of patients enrolled in a registry. A table of the numbers of registrants by year would be an informative figure. We need more organized systems to improve participation.</p>	\$13,590,660
<p>7D. Establish and maintain an international network of biobanks for the collection of brain tissue, fibroblasts for pluripotent stem cells, and other tissue or biological material, by acquisition sites that use standardized protocols for phenotyping, collection, and regulated distribution of limited samples by 2011.</p> <ul style="list-style-type: none"> This includes support for post-processing of tissue, such as genotyping, RNA expression profiling, and MRI. Protocols should be put into place to expand the capacities of ongoing large-scale children's studies to collect and store additional biomaterials, including newborn bloodspots, promoting detection of biological signatures. Support should also be provided to develop an international web-based digital brain atlas that would provide high-resolution 3-D images and quantitative anatomical data from tissue of patients with ASD and disease controls across the lifespan, which could serve as an online resource for quantitative morphological studies, by 2014. 	<p>Funding: The recommended budget was partially met.</p> <p>Progress: NIH launched a new multi-disorder Neurobiobank initiative in 2013. The \$5M effort encompasses autism and other brain disorders, and thus may not be reflected in the portfolio analysis in 2013. A private effort, the Autism Brain Net, is also underway, with several sites governed by a scientific board which awards samples based on scientific merit. Though these two efforts represent progress, more work is needed to increase the amount of tissues available and to ensure good stewardship of these resources. The Brainspan Atlas, supported by the Allen Brain Institute and a consortium of government and private funders, provides a useful source of information on gene expression in the brain during development, but the project is not reflected in the 2008-2012 funding figures because it is not autism specific. In 2009, NIH supported the atlas with \$18.4 M dollars and in 2010, NIH provided \$16.5M. This publicly availability of this atlas will be transformative for the field of developmental neuroscience. The NIMH Genetics Repository is another resource that has continued to grow to meet the needs of researchers in many fields, including ASD research. Current sample numbers in the repository are: 27,000 DNA samples, 16,000 samples that have been processed and prepared for distribution, 6,200 cases of autism are represented. There are 20 fibroblast lines and 25 iPS cell lines.</p> <p>Remaining Gaps, Needs and Opportunities: While progress has been made in establishing, maintaining and expanding tissue resources for research, this is still an area of enormous need. There may be fewer brain samples available</p>	\$24,752,287

	<p>for study currently than there were at the inception of the Strategic Plan due to the failure of a freezer at a major brain bank in 2012, which resulted in the loss of a large number of ASD brain specimens. There is still a need for tissue and brains from typically developing or neurotypical controls. Compared to other disorders, the number of tissue samples available for ASD research is quite low.</p>	
<p><i>IACC Recommended Budget: \$82,700,000 over 5 years (revised in 2011)</i> 7E. Begin development of a web-based toolbox to assist researchers in effectively and responsibly disseminating their findings to the community, including people with ASD, their families, and health practitioners by 2011.</p>	<p>Funding: The recommended budget was met but few projects were categorized to this objective. Progress: This objective has been partially achieved in terms of projects funded, but not through a web-based toolbox. Dissemination of findings has taken place through other efforts. For example, the “Data from Papers” feature in NDAR connects readers from the Pubmed citation of a study to the actual data deposited in the database. Several organizations and groups (Simons Foundation, Autism Speaks, ASF, IAN, CDC) publish lay-friendly summaries of recent scientific findings online, as well as lay-friendly versions of their reports. Remaining Gaps, Needs and Opportunities: Access to information about research findings remains a problem for those communities that are resource-poor and do not have internet access. In addition, the lack of open access to most peer-reviewed journals also limits the public’s ability to access fully detailed information about new findings.</p>	<p>\$1,254,150</p>
<p><i>IACC Recommended Budget: \$400,000 over 2 years</i> 7F. Create funding mechanisms that encourage rapid replication studies of novel or critical findings by 2011.</p>	<p>Funding: The recommended budget has not been met and there are no projects categorized to this objective. Progress: The Planning Group discussed the issue that creation of funding mechanisms is not likely to be achieved through grant funding, and therefore would not be reflected in the grant portfolio. Remaining Gaps, Needs and Opportunities: The committee still feels that this objective is relevant and that it is not too early to begin replication studies. In the databases there are 70,000 subjects, 7,000 exomes and 2,500 MRIs that can be used for replication analysis. The intent of the objective was to quickly replicate findings related to potential treatments, but to date, no special fast-track funding mechanisms have been set up to support this.</p>	<p>\$0</p>
<p><i>No recommended budget assigned by the IACC</i> 7G. Develop a web-based tool that provides population estimates of ASD prevalence for States based on the most recent prevalence range and average identified by the ADDM Network by 2012.</p>	<p>Funding: Autism tracking data is captured in CDC’s environmental tracking tool and is not reflected in the autism grant portfolio figure because it is a general tool that encompasses multiple disorders and conditions. Progress: The intent of this objective has been accomplished through the CDC project and can be considered completed. Remaining Gaps, Needs and Opportunities: No new needs or opportunities in this area were identified.</p>	<p>\$0</p>
<p><i>IACC Recommended Budget: \$200,000 over 2 years</i> 7H. Create mechanisms to specifically support the contribution of data from 90% of newly initiated projects to the National Database for Autism Research (NDAR), and link NDAR with other existing data resources by 2012.</p>	<p>Funding: The recommended budget has been met for this objective. Progress: The objective to create mechanisms to support the contribution of data from newly initiated projects to NDAR has been met, and NDAR has linked with several other existing data sources such as the ATP, AGRE and IAN. In 2012, 81% of NIH-funded extramural studies were contributing data to NDAR. All NIH grants have terms that require linking of data to NDAR. (Dan Hall (NDAR) can provide a table of the participation numbers across the years.) Remaining Gaps, Needs and Opportunities: Infrastructure will need continued development enabling both leading and novel scientific computational pipelines to be made more generally available on the cloud, moving computation – and the virtually unlimited resources available there – to the data, which is now much too large to effectively move. IAN data collection could be expanded to include locations of residence to enable geographic data collection on environmental exposures.</p>	<p>\$9,583,653</p>
<p><i>IACC Recommended Budget: \$6,800,000 over 2 years</i> 7I. Supplement existing ADDM Network sites to use population-based</p>	<p>Funding: The recommended budget has been met and the research goals in</p>	<p>\$23,810,274</p>

<p>surveillance data to conduct at least five hypothesis-driven analyses evaluating factors that may contribute to changes in ASD prevalence by 2012.</p> <p><i>IACC Recommended Budget: \$660,000 over 2 years</i></p>	<p>the objective have been achieved. Progress: Initially supplements were needed to support these analyses, but now the ADDM sites are well established and are conducting some analyses using funds from the ADDM grants themselves, and outside supplements are supporting other additional analyses. Remaining Gaps, Needs and Opportunities: Supplements remain an opportunity to capitalize on this infrastructure. (Note that the funding amount for this objective reflects the full funding of the ADDM sites and not just the supplements.)</p>	
<p>7J. Develop the personnel and technical infrastructure to assist States, territories, and other countries that request assistance describing and investigating potential changes in the prevalence of ASD and other developmental disabilities by 2013.</p> <p><i>IACC Recommended Budget: \$1,650,000 over 3 years</i></p>	<p>Funding: The recommended budget was partially met. The Autism Speaks Global Health Initiative projects have been coded to their specific scientific areas and are not represented in this funding amount, but they also contribute toward this objective. The CDC provides personnel and help to States, territories and countries as requested but the budget for that assistance is not reflected in the portfolio analysis figures because this work is not done through grants. Progress: Some progress has been made in addressing this need, but it was not reflected in the funding amount because it was conducted through sources not catalogued in the portfolio analysis or the projects were assigned according to their scientific topics rather than to this objective. In addition to providing supplemental funding for ADDM site surveillance, Autism Speaks funds projects on surveillance conducted by sites outside of the ADDM network for example the Kwa-Zulu-Natal Autism Study in South Africa Remaining Gaps, Needs and Opportunities: While progress has been achieved, ongoing efforts are needed in this area.</p>	<p>\$1,369,963</p>
<p>7K. Encourage programs and funding mechanisms that expand the research workforce, enhance interdisciplinary research training, and recruit early-career scientists into the ASD field by 2013.</p> <p><i>IACC Recommended Budget: \$1,650,000 over 3 years</i></p>	<p>Funding: The recommended budget was met for this objective. Many of the fellowships are coded according to the specific topic of the research conducted and thus are not represented in this funding figure. Progress: In 2008, NIH supported 46 autism related training/fellowship grants (\$5.1 million dollars), and in 2012 NIH supported 78 such grants (\$7.7 million dollars). Remaining Gaps, Needs and Opportunities: This objective should continue to be encouraged with a possible future emphasis on services-based research.</p>	<p>\$24,702,276</p>
<p>7L. Expand the number of ADDM sites in order to conduct ASD surveillance in children and adults; conduct complementary direct screening to inform completeness of ongoing surveillance; and expand efforts to include autism subtypes by 2015.</p> <p><i>IACC Recommended Budget: \$5,000,000 over 3 years</i></p>	<p>Funding: The recommended budget was partially met, but it is noted that the full funding of the ADDM sites is reflected in Objective 7I and thus there may be underrepresentation in this category. Progress: Supplements have been provided to 6 ADDM sites by CDC to collect data from a younger cohort (4 year olds) in addition to the 8 year olds currently studied, 2 other ADDM sites have received supplements from CDC to conduct surveillance studies among 15 to 18 year olds. While these expansions have occurred, further work is needed to better understand prevalence in both younger and older populations. Currently at UNC there is a reassembly of those who participated in TEACCH to conduct a study of long-term outcomes. Also, Paul Shattuck has published studies on young adults with disabilities seeking services that have revealed a significant drop in services use and access post high school along with an increased likelihood to remain living with a parent or guardian. In addition, the Utah cohort (mentioned in Question 6) has also been used for studies related to adults with autism, with a recent paper identifying health risks and causes of mortality. Remaining Gaps, Needs and Opportunities: While subtypes were included as part of this objective, with the changes in the DSM to eliminate subtypes, this portion of the objective may no longer be relevant. In the future it may be more useful to collect data on characteristics of children or other adults with ASD who participate in studies.</p>	<p>\$3,681,460</p>
<p>7M. Support 10 "Promising Practices" papers that describe innovative and successful services and supports being implemented in communities that benefit the full spectrum of people with ASD, which can be replicated in other communities, by 2015.</p> <p><i>IACC Recommended Budget: \$16,200,000 over 5 years</i></p>	<p>Funding: The recommended budget was not met for this objective based on projects reported. Progress: Information was requested from CMS about the program that produced the earlier promising practices papers; it is possible that the</p>	<p>\$0</p>

	<p>program is no longer funded and that priorities have shifted to other methods of disseminating best practices information. Remaining Gaps, Needs and Opportunities: Best practices information dissemination is still a high priority, but there may be other means by which this is being done. The focus is more on achieving dissemination than on the particular method used.</p>	
<p><i>IACC Recommended Budget: \$75,000 over 5 years</i> 7N. Enhance networks of clinical research sites offering clinical care in real-world settings that can collect and coordinate standardized and comprehensive diagnostic, biological (e.g., DNA, plasma, fibroblasts, urine), medical, and treatment history data that would provide a platform for conducting comparative effectiveness research and clinical trials of novel autism treatments by 2012.</p>	<p>Funding: The recommended budget was met/exceeded for this objective, and several projects were categorized to this objective. Progress: Autism Speaks' ATN is a care network that also has research capabilities. The ATN has a collection of biological samples collected from patients who have sought care at the ATN, but the samples are not broadly shared like those from other repositories and the samples were not collected systematically to support specific kinds of studies. As the ATN has progressed in its work, has shifted away from the goal of creating a repository to a new focus on developing clinical guidelines, especially in the area of co-occurring conditions. Several guidelines have been published. Another network, the Interactive Autism Network (IAN), has piloted a new rapid method of conducting "virtual" clinical trials of low-risk or "safe" treatments. For example, IAN conducted a trial on omega 3 fatty acids – a commonly used dietary supplement - across 40 states in 10 weeks, demonstrating the value of using interactive research networks for these types of trials. Remaining Gaps, Needs and Opportunities: Clinical and patient social networks represent new ways to do research ("practice to research"), and an intervention that does not require extensive safety testing (e.g., alternate diets or technological interventions) can be evaluated quickly using the large social networks.</p>	<p>\$19,353,505</p>
<p><i>IACC Recommended Budget: \$1,850,000 over 1 year</i> 7O. Create an information resource for ASD researchers (e.g., PhenX Project) to share information to facilitate data sharing and standardization of methods across projects by 2013.</p> <ul style="list-style-type: none"> • This includes common protocols, instruments, designs, and other procedural documents and should include updates on new technology and links to information on how to acquire and utilize technology in development. • This can serve as a bidirectional information reference, with autism research driving the development of new resources and technologies, including new model systems, screening tools, and analytic techniques. 	<p>Funding: The recommended budget was met, with a small number of projects funded. Progress: NDAR has developed a data dictionary that is now widely used across the research community to standardize data terminology so that researchers know what they are accessing. Funding for this project is not reflected in the total for this objective because NDAR is coded elsewhere. NDAR also has a human subject common identifier that is now broadly used by the community. Remaining Gaps, Needs and Opportunities: Funding is necessary to develop standardized methods and protocols. This is a long term project and will need to be approached carefully.</p>	<p>\$2,404,279</p>
<p><i>IACC Recommended Budget: \$2,000,000 over 2 years</i> 7P. Provide resources to centers or facilities that develop promising vertebrate and invertebrate model systems, and make these models more easily available or expand the utility of current model systems, and support new approaches to develop high-throughput screening technologies to evaluate the validity of model systems by 2013.</p>	<p>Funding: The recommended budget was met for this objective. Progress: When mouse models are made, they are shared via Jackson Labs. Other model organisms are shared even more widely. Remaining Gaps, Needs and Opportunities: Emphasis on this objective is still required to advance basic and translational ASD research.</p>	<p>\$1,588,780</p>
<p><i>IACC Recommended Budget: \$1,100,000 over 2 years</i> Core Activities</p>		<p>\$43,431,065</p>
<p>Total funding for Question 7</p>		<p>\$158,028,308</p>