

SAFEMINDS EVALUATION OF IACC BUDGET
Green denotes SafeMinds Recommendations, Red denotes IACC future action

Objective	IACC Budget Recommendation	SM Budget Estimates	SafeMinds Recommendations & Comments
1. When Should I Be Concerned?			
Short-Term Objectives			
ST 1.1 - Develop, with existing tools, at least one efficient diagnostic instrument (e.g., briefer, less time intensive) that is valid in diverse populations for use in large-scale studies by 2011.	5,300,000		
ST 1.2 - Validate and improve the sensitivity and specificity of new or existing screening tools for detecting ASD through studies of the following community populations that are diverse in terms of age, socio-economic status, race, ethnicity and level of functioning by 2012. o School aged children o General population (vs. clinical population)	5,400,000		
ST 1.3 Conduct active screening prevalence studies, in a number of U.S. locations and using a variety of sampling approaches, of adults born before 1987 and compare it with prevalence of teenagers born during or after 1987, using the same diagnostic criteria, and assess whether adult phenotype differs from teenage phenotype.		\$6,000,000	Rigorous prevalence studies of adults are needed to confirm the contribution of the environment relative to diagnostic changes to the recent rise in autism cases, to assess whether the subtypes of ASD have changed over time by birth cohort as well as due to age, and to determine the need for services for adults alive today, including the need for rapid screening of adults so that they can get the services most effective for ASD.
Long-Term Objectives			
LT 1.1 - Identify a panel of biomarkers that separately, or in combination with behavioral measures, accurately identify, before age 2, one or more subtypes of children at risk for developing ASD by 2014.	33,300,000		Short-term biomarker development needed.
LT 1.2 - Develop at least five measures of behavioral and/or biological heterogeneity in children or adults with ASD, beyond variation in intellectual disability, that clearly relate to etiology and risk, treatment response and/or outcome by 2015.	71,100,000		
LT 1.3 - Identify and develop measures to assess at least three continuous dimensions of ASD symptoms and severity that can be used by practitioners and/or parents to assess response to intervention for people with ASD across the lifespan by 2016. IACC Recommended Budget: \$18,500,000 over 5 years.	18,500,000		
LT 1.4 - Effectively disseminate at least one valid and efficient diagnostic instrument (e.g., briefer, less time intensive) in general clinical practice by 2016. Duration 5 years			Deferred until 2009 strategic planning update. Dissemination (as opposed to dissemination research) should not be part of the IACC SP budget.
TOTAL Question 1	133,600,000	\$139,600,000	

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2. How Can I Understand What Is Happening?			
Short-Term Objectives			
ST 2.1 - Establish an international network of biobanks for the collection of brain and other tissue (e.g., skin fibroblasts) with acquisition sites that use standardized protocols for phenotyping, collection and distribution of tissue by 2011.	10,500,000	\$40,000,000	Several biobanks managed by a variety of institutions should be supported. Extensive resources with many patients, family members and controls will cost far more than \$5 million. A more realistic and effective budget would be \$40 million.
ST 2.2 - Support at least four research projects to identify mechanisms of metabolic and/or immune system interactions with the central nervous system that may underlie the development of ASD during prenatal-postnatal life by 2010.	9,800,000	\$40,000,000	Four research projects to understand the biology of autism that can inform causality and lead to treatments are insufficient. Topics should include but not be limited to immune and metabolic. The number should be at least 25 and the budget increased accordingly. NIEHS should be the lead agency for many of these projects.
ST 2.3 - Launch three studies that specifically focus on the neurodevelopment of females with ASD by 2011.	8,900,000		
ST 2.4 - Identify ways to increase awareness among the autism spectrum community of the potential value of brain and tissue donation to further basic research.	1,400,000		
Long-Term Objectives			
LT 2.1 - Complete a large-scale, multi-disciplinary, collaborative project that longitudinally and comprehensively examines how the biological, clinical, and developmental profiles of children, with a special emphasis on females, youths, and adults with ASD change over time as compared to typically developing people by 2020.	126,000,000		
LT 2.2 - Maintain an international network of biobanks and support continued collection of brain and other tissue by 2014.	22,000,000		
Total Question 2	178,600,000	\$238,300,000	
3. What Caused This To Happen & Can This Be Prevented?			
Short-Term Objectives			
ST 3.1 -Initiate studies on at least five environmental factors identified in the recommendations from the 2007 IOM report "Autism and the Environment: Challenges and Opportunities for Research" as potential causes of ASD by 2010.	23,600,000	\$56,000,000	Studying only 5 environmental factors is inadequate. The public members of IACC voted for expansion to 20 factors, with a corresponding increase in budget, and should cover interaction between exposures, not single exposures exclusively. Mercury in its various and cumulative forms should be explicitly made an exposure for study. Populations in the U.S. and not just those in other countries should be used. NIEHS should be the lead agency for this initiative.
ST 3.2 - Coordinate and implement the inclusion of approximately 20,000 subjects for genome-wide association studies, as well as a sample of 1,200 for sequencing studies to examine more than 50 candidate genes by 2011.	43,700,000	\$0	Genetic research is well funded by private organizations and NIH should invest monies into understudied role of environmental factors and their genetic interplay.
ST 3.3 - Within the highest priority categories of exposures for ASD, identify and standardize at least three measures for identifying markers of environmental exposure in biospecimens by 2011.	3,500,000	\$30,000,000	IACC Public members voted to increase the number of biomarkers and the budget, but were out voted by Federal members. Given the number of potential biomarkers, exposures, and subtypes. Environmental research is underfunded but is the most likely to lead to effective treatments and prevention. Each biomarker is expected to cost \$2 million. The number of biomarkers should increase to 10 and the dollars budgeted to \$30 million. Autism Research Institute should be part of this initiative.

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3. What Caused This To Happen & Can This Be Prevented? (cont.)			
Short-Term Objectives			
ST 3.4 Study the effect of vaccines, vaccine components, and multiple vaccine administration through a variety of approaches, including cell and animal studies, and understand whether and how certain subpopulations in humans may be more susceptible to adverse effects of vaccines by 2011. Duration 2 years		\$6,000,000	Passed in December, stripped from agenda in January under false premise and apparent violation of Federal Advisory Committee Act. False premise: concerns regarding the IACC's mandate; government agency conflicts of interest in ongoing vaccine injury litigation; NIH lack of expertise to conduct vaccine research; and that these objectives did not originate from IACC science workshops. These objectives were cited as fitting into IACC Science Workshop Initiative 34 in IACC transcripts of 2/08. NIH conducts extensive vaccine reseach with over 400 in currety in progress. Due to admission of conflicts of interest, independent oversight and investigators are required to fulfill this objective.
ST 3.5 Determine the feasibility and design an epidemiological study to determine if the health outcomes, including ASD, among various populations with vaccinated, unvaccinated and alternatively vaccinated groups by 2011. Duration 2 years		\$10,000,000	Passed in December and stripped from agenda in January. Was originally worded as initiating an epidemiological study and approved as a feasibility study. See comments on ST 3.4 for additional information.
ST 3.4 - Enhance existing case-control studies to enroll broad ethnically diverse populations affected by ASD by 2011.	3,300,000		Must include U.S. Populations
Long-Term Objectives			
LT 3.1 - Determine the effect of at least five environmental factors on the risk for subtypes of ASD in the pre- and early postnatal period of development by 2015.	25,100,000	\$50,000,000	All IACC Public Members voted for an increase to 20 environmental factors, but were out voted by Federal members. Should include exposure/exposure and exposure/pathogen mixtures. Some of these studies could be started immediately. Populations in the U.S. such as CHARGE, and not just those in other countries, should be used. NIEHS should be the lead agency for this initiative. Studying only 5 environmental factors, and solely as a long-term initiative, is inadequate.
LT 3.2 - Conduct a multi-site study of the subsequent pregnancies of 1,000 women with a child with ASD to assess the impact of environmental factors in a period most relevant to the progression of ASD by 2014.	11,100,000		Public IACC members voted for this item with the inclusion of monitoring environmental toxicants prenatally and for first 3 years of life with methods comparable to the national Children's Study. Federal members out voted public members. The period of interest should be specified as the pre-natal and the first 3 years of life.
LT 3.3 - Identify genetic risk factors in at least 50% of people with ASD by 2014.	33,900,000	\$0	Genetic research is well funded by private organizations and NIH should invest monies into understudied role of environmental factors and their genetic interplay.
LT 3.4 - Support ancillary studies within one or more largescale, population-based surveillance and epidemiological studies, to collect nested, including U.S. populations, case-control data on environmental factors during preconception, and during prenatal and early postnatal development, as well as genetic data, that could be pooled (as needed), to analyze targets for potential gene/environment interactions by 2015. Duration over 5 years	44,400,000	\$50,000,000	A higher dollar estimate is needed to adequately address this issue, especially given the underfunding of environmental factors and the interaction between genetic susceptibility and exposures. It is important that U.S. populations be utilized for much of this work and that multiple approaches and investigator teams are used.
TOTAL QUESTION 3	188,600,000	\$216,400,000	

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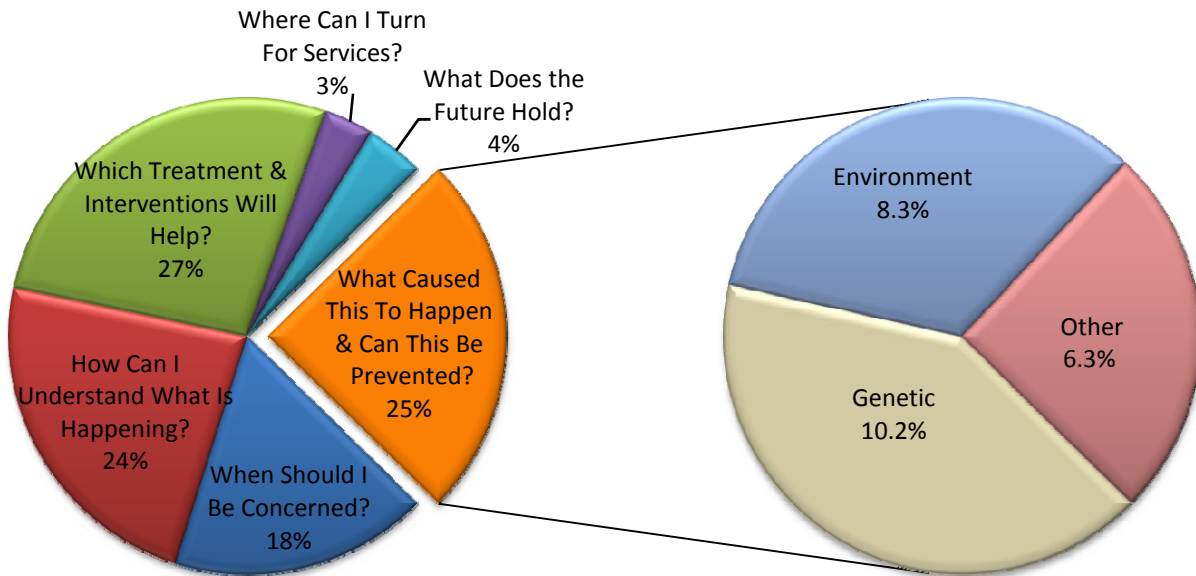
Objective	IACC Budget Recommendation	SM Budget Estimates	SafeMinds Recommendations & Comments
4. Which Treatment & Interventions Will Help?			
Short-Term Objectives			
ST 4.1 - Launch at least four research projects that seek to identify biological signatures that measure significant changes in ASD core symptoms across the lifespan by 2010.	12,700,000	\$28,000,000	Treatment research is desperately needed. Public IACC Members voted to quadruple the number of projects and were out voted by Federal members.
ST 4.2 - Support at least three randomized controlled trials that address co-occurring medical conditions associated with ASD by 2010.	13,400,000	\$30,000,000	Treatment research is desperately needed. Public IACC Members voted to quadruple the number of projects and were out voted by Federal members.
ST 4.3 - Conduct five randomized controlled trials of early intervention for infants and toddlers by 2011.	16,700,000		
ST 4.4 - Launch three randomized controlled trials of interventions for school-aged and/or adolescents by 2012.	15,600,000		
ST 4.5 - Standardize and validate at least 20 model systems (e.g. cellular and/or animal) that replicate features of ASD and will allow identification of specific molecular targets or neural circuits amenable to existing or new interventions by 2012.	75,000,000		
ST 4.6 - Test safety and efficacy of at least five widely used interventions (e.g., nutrition, medications, medical procedures, etc.) that have not been rigorously studied for use in ASD by 2012.	27,800,000	\$60,000,000	Treatment research is desperately needed. Public IACC Members voted to quadruple the number of projects and were out voted by Federal members.
ST 4.7 - Complete two multi-site randomized controlled trials of comprehensive early intervention that address core symptoms, family functioning and community involvement by 2013.	16,700,000		
Long-Term Objectives			
LT 4.1 - Complete at least three randomized controlled trials on medications targeting core symptoms in people with ASD of all ages by 2014	22,200,000	\$36,000,000	Treatment research is desperately needed. Public IACC Members voted to quadruple the number of projects and were out voted by Federal members.
LT 4.2 - Develop interventions for siblings of people with ASD with the goal of reducing risk recurrence by at least 30% by 2014.	6,700,000		
TOTAL QUESTION 4	206,800,000	\$284,700,000	
5. Where Can I Turn For Services?			
Short-Term Objectives			
ST 5.1 - Initiate a "State of the States" assessment of existing state programs and supports for people and families living with ASD by 2009. Duration 2 years	\$630,000		
ST 5.2 - Support two studies that assess how variations and access to services affect family functioning in diverse populations by 2012.	\$1,000,000		
Long-Term Objectives			
LT 5.1 - Test the efficacy and cost-effectiveness of at least four evidence-based services for people with ASD of all ages in community settings by 2015.	16,700,000		
LT 5.2 - Test four methods to improve dissemination of effective interventions in diverse community settings by 2013.	7,000,000	\$11,500,000	
TOTAL QUESTION 5	\$25,330,000	\$29,830,000	

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6. What Does the Future Hold?			
ST 6.1 - 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.	1,300,000	\$2,400,000	This amount should increase as there are a number of promising data sets that could be utilized if the funding were available. In addition to NDAR, the ARI/DAN data set should be linked.
ST 6.2 - Launch at least two studies to assess and characterize variation in adults living with ASD (e.g., social and daily functioning, demographic, medical and legal status) by 2011.	5,000,000		
ST 6.3 - Conduct at least two clinical trials to test the efficacy and cost-effectiveness of interventions, services and supports to optimize daily functioning (e.g., educational, vocational, recreational, and social experiences) for adolescents, adults, or seniors living with ASD by 2012.	8,000,000	\$7,500,000	At these 3 clinical trials should be launched, as there are numerous interventions in use now that could be tested.
ST 6.4 - Conduct a needs assessment to determine how to merge or link administrative and surveillance databases that allow for tracking the involvement of individuals living with ASD research in health care, education, and social services by 2009.	520,000		
Long-Term Objectives			
LT 6.1 - Develop at least two community-based interventions with individual specificity that improves outcomes, as measured by educational, occupational, and social achievements by 2015.	12,900,000		
LT 6.2 - Develop and have available to the research community means by which to merge or link administrative databases that allow for tracking the involvement of people living with ASD research in health care, education, and social services by 2018.	tba		
LT 6.3 - Conduct a cost/benefit analysis on provision of services and interventions over the lifespan with regard to long-term benefits including employment, productivity, and the need for federal/state assistance.	2,300,000		
TOTAL QUESTION 6	\$30,020,000	\$30,620,000	
GRAND TOTAL	\$762,950,000	\$939,450,000	CAA IACC Budget \$645 million, current IACC budget 18% over, SM 46% over
Percent of Budget			
1. When Should I Be Concerned?	18%	15%	
2. How Can I Understand What Is Happening?	23%	25%	
3. What Caused This To Happen & Can It Be Prevented	25%	23%	
4. Which Treatments & Interventions Will Help?	27%	30%	
5. Where Can I Turn For Services?	3%	3%	
6. What Does the Future Hold?	4%	3%	

IACC Budget Breakdown

Total Budget \$762,950,000



SafeMinds IACC Budget Recommendation

Total Budget \$939,450,000

