Interagency Autism Coordinating Committee (IACC) Strategic Planning Implementation Workgroup Meeting

September 10, 2008

11AM – 3PM Eastern

Public Conference Call Information

– Phone Number:	888-455-2920
– Access Code:	3857872

IACC Strategic Planning Implementation Workgroup Meeting

The meeting will begin soon!

You may access audio using the public conference call line:

Phone Number: 888-455-2920
Access Code: 3857872

Meeting Agenda

11:00 – 11:15 am EDT	Welcome and Introductions
11:15 – 11:45	Question 1 Costs, Organizations, and Milestones
11:45 – 12:15 pm EDT	Question 2 Costs, Organizations, and Milestones
12:15 – 12:45	Question 3 Costs, Organizations, and Milestones
12:45 – 1:15	Lunch Break
1:15 – 1:45	Question 4 Costs, Organizations, and Milestones
1:45 – 2:15	Question 5 Costs, Organizations, and Milestones
2:15 – 2:45	Question 6 Costs, Organizations, and Milestones
2:45 – 3:00	Summary

Implementation Workgroup

Formed to advise the IACC about:

- The budgetary requirements needed to complete and fulfill the research objectives described in the IACC Strategic Plan for Autism Spectrum Disorders (ASD) Research
- The agencies and organizations that will be accountable for launching initiatives within the plan for open competition and peer-review

Organizations and Individuals To Be Represented

Federal Funders of ASD Research

Centers for Disease Control and Prevention (CDC)

Centers for Medicare and Medicaid Services (CMS)

Department of Defense (DoD)

Department of Education (ED)

Health Resources and Services Administration (HRSA)

National Institutes of Health (NIH)

Private Funders of ASD Research

Autism Consortium

Autism Speaks

Autism Research Institute (ARI)

Organization for Autism Research (OAR)

Southwest Autism Research and Resource Center (SARRC)

The Simons Foundation (Simons)

People Affected by ASD

Person with an ASD

Family member of a person with an ASD

Today's Participants

Federal Funders of ASD Research

Ed Trevathen (CDC)

Marshalyn Yeargin-Allsopp (CDC)

Cathy Rice (CDC)

Ellen Blackwell (CMS)

Gail Houle (ED)

Duane Alexander (NIH/NICHD)

Alice Kau (NIH/NICHD)

James Hanson (NIH/NICHD)

James Battey (NIH/NIDCD)

Judith Cooper (NIH/NIDCD)

Cindy Lawler (NIH/NIEHS)

Lisa Gilotty (NIH/NIMH)

Ann Wagner (NIH/NIMH)

Story Landis (NIH/NINDS)

Laura Mamounas (NIH/NINDS)

Person with an ASD

Wolf Dunaway

Private Funders of ASD Research

Patricia Tanski (Autism Consortium)
Alan Crane (Autism Consortium)
Elizabeth Mumper (ARI)
Doreen Granpeesheh (ARI)
Peter Bell (Autism Speaks)
Andy Shih (Autism Speaks)
Peter Gerhardt (OAR)
Denise Resnick (SAARC)
Raun Melmed (SAARC)
Marta Benedetti (Simons Foundation)

Family Member of a Person with ASD

Christine McKee

Chairperson

Thomas Insel (NIH/NIMH)

Designated Federal Official

Della Hann (NIH/NIMH)

Goals for Today’s Meeting

- Discuss estimates from the 1st Implementation Meeting
  - Refine the cost estimates developed at the first meeting
  - Confirm/refine number of years of funding
  - Define start year for each objective
  - Identify any objectives that are unclear
- Identify organizations
  - For each objective, identify organizations interested in funding initiatives
- Define initial milestones and measures of accountability

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Q1. WHEN SHOULD I BE CONCERNED?

Short-Term Objectives

- 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. ***(2 years, $2.5M)***
- Validate and improve the sensitivity and specificity of 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. ***(3 years, $5M)***
  -School aged children
  -General population (vs. clinical population)

Long-Term Objectives

- Validate 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. ***(5 years, $30M)***
- Develop 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. ***(5 years, $40M)***
- Identify and develop measures to assess at least three continuous dimensions of ASD symptoms and severity that can be used to assess response to intervention for individuals with ASD across the lifespan by 2016. ***(5 years, $1.5M-$10M)***
- Effectively disseminate at least one valid and efficient diagnostic instrument (e.g., briefer, less time intensive) in general clinical practice by 2016. ***(5 years, $5M-$10M)***

Q2. HOW CAN I UNDERSTAND WHAT IS HAPPENING?

Short-Term Objectives

- Establish an international network of brain and other tissue (e.g., skin fibroblasts) acquisition sites with standardized protocols for phenotyping, collection and distribution of tissue by 2010. ***(2 years, $5M)***
- 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. ***(4 years, $6M)***
- Launch three studies that specifically focus on the neurodevelopment of females with ASD by 2011. ***(5 years, $8M)***

Long-Term Objectives

- Complete a large-scale, multi-disciplinary, collaborative project that longitudinally and comprehensively examines how the biological, clinical, and developmental profiles of children, youths, and adults with ASD change over time as compared to typically developing individuals by 2020.
(12 years, $50M-$100M)

Q3. WHAT CAUSED THIS TO HAPPEN AND CAN THIS BE PREVENTED?

Short-Term Objectives

- 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. ***(2 years, $14M)***
- 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. ***(4 years, $40M)***
- Within the highest priority categories of exposures for ASD, validate and standardize at least three measures for identifying markers of environmental exposure in biospecimens by 2011. ***(3 years, $600k-$9M)***

Long-Term Objectives

- 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 2012. ***(5 years, $10M)***
- Conduct a multi-site study of the subsequent pregnancies of 1000 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. ***(5 years, $10M)***
- Identify genetic risk factors in at least 50% of children with ASD by 2014. ***(6 years, $30M-$150M)***
- Support ancillary studies within one or more large-scale, population-based epidemiological studies, to collect nested, 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. ***(5 years, $5M-$40M)***

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The meeting will resume at approximately 1:05 p.m.

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Q4. WHICH TREATMENTS AND INTERVENTIONS WILL HELP?

Short-Term Objectives

- Launch four research projects that seek to identify biological signatures that measure significant improvement in ASD core symptoms across the lifespan by 2010. ***(4 years, $7M)***
- Support three randomized controlled trials that address co-occurring medical conditions associated with ASD by 2010. ***(3 years, $7.5M)***
- Conduct five randomized controlled trials of early intervention for infants and toddlers by 2011. ***(5 years, $15M)***
- Launch three randomized controlled trials of interventions for school-aged and/or adolescents by 2012. ***(3 years, $1.5M-$1.8M)***
- Standardize and validate three 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. ***(5 years, $15M)***
- Test safety and efficacy of five widely used interventions (e.g., nutrition, medications, medical procedures, etc.) that have not been rigorously studied for use in ASD by 2012. ***(5 years, $15M)***
- Complete two multi-site randomized controlled trials of comprehensive early intervention that address core symptoms, family functioning and community involvement by 2013. ***(5 years, $15M)***

Long-Term Objectives

- Complete randomized controlled trials in humans on three medication targeting core symptoms by 2014. ***(5 years, $7.5M)***
- Develop interventions for siblings of people with ASD with the goal of reducing risk recurrence by at least 30% by 2014. ***(5 years, $6M)***

Q5. WHERE CAN I TURN FOR SERVICES?

Short-Term Objectives

- Initiate a “state of the states” assessment of existing state programs and supports for people and families living with ASD by 2009. ***(1 year, $300k)***
- Support two studies that assess how variations and access to services affect family functioning in diverse populations by 2012. ***(3 years, $900k)***

Long-Term Objectives

- Test four methods to improve dissemination of effective interventions in diverse community settings by 2013. ***(5 years, $6.3M)***
- Test the efficacy and cost-effectiveness of three evidence-based services for people with ASD of all ages in community settings by 2015. ***(5 years, $7.5M-$10M)***

Q6. WHAT DOES THE FUTURE HOLD?

Short-Term Objectives

- Develop and have available to the research community means by which to merge or link databases that allow for tracking the involvement of individuals in ASD research by 2010. ***(2 years, $1.2M)***
- 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. ***(3 years, $1.5M)***
- 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. ***(5 years, $5M)***

Long-Term Objectives

- Develop at least two community-based interventions with individual specificity that improves outcomes, as measured by educational, occupational, and social achievements by 2015. ***(5 years, $8M)***
- Develop and have available to the research community means by which to merge or link administrative databases that allow for tracking the involvement of individuals living with ASD research in health care, education, and social services by 2018. ***(1 year, $500k)***