NIH Update

William Riley, Ph.D.
Director, NIH Office of Behavioral and Social Sciences Research
Background and Strategic Plan

OBSSR
OBSSR Roots – 1997 Strategic Plan

• Enhance Behavioral and Social Sciences Research and Training
• Integrate Biobehavioral Perspectives in All NIH Research Areas
• Improve Communications Among Behavioral and Social Science Researchers and the Public
2007 OBSSR Strategic Prospectus

• **Basic Science**
  – Develop consensus on priority research areas
  – Encourage T1 research
  – Develop research infrastructure

• **Interdisciplinary Research**
  – Provide education and training in interdisciplinary research
  – Strengthen methods and analyses to better support interdisciplinary research

• **Systems Science**
  – Contribute to the development of analytical approaches
  – Contribute to curriculum development in systems thinking and tools

• **Population Impact**
  – Develop standards of evidence for reporting findings
  – Facilitate a dialogue among researchers regarding the nature of evidence
Strategic Planning Process and Timeline

Sept:  Internal Retreats
Oct:   BSSR-CC and Strategic Plan Workgroup meetings
Nov:   RFI on BSSR Challenges
Jan:   Expert Panel Meeting and IC meetings
Feb:   Begin Draft of Strategic Plan
Mar:   RFI and Webinars
Mar:   Finalize Plan

Strategic Plan Working Group
Wilson Compton (NIDA)
Bob Croyle (NCI)
Larry Fine (NHLBI)
James Griffin (NICHD)
Christine Hunter (NIDDK)
David Murray (ODP)
Lis Nielsen (NIA)
Kevin Quinn (NIMH)
Karyl Swartz (CSR)
Guiding Principles for 2016 Strategic Plan

• Integration of BSSR into the broader biomedical research efforts consistent with the NIH mission
• Coordination and collaboration with ICs
• Identify critical challenges that are barriers to advancement in BSSR (most impact to the largest proportion of behavioral and social science researchers)
• Focus on challenges that OBSSR is *uniquely* poised to address (if OBSSR didn’t exist, it would not get done)
Three Key Themes Emerging from Initial Efforts

• **Advance the measurement of behavior and its influences**
  – Accurate, temporally dense measurement of behavior (tech)
  – Measurement of higher level constructs (family, community, etc.)
  – Analytic approaches that better match new measurement methods

• **Promote a cumulative intervention science**
  – Behavioral taxonomy/ontology
  – Facilitate a basic to applied pipeline
  – General principles of behavior change and their bounds
  – Improved methods for evaluating intervention components
  – Adaptive intervention methods
  – Dissemination of robust, scalable, generalizable interventions

• **Integrate behavioral science in new areas of biomedical research**
  – Behavioral epigenetics
  – Large longitudinal cohort studies
  – Comorbidities
  – Transdisciplinary teams
How Does OBSSR Meet Its Objectives?

• Identify gaps and issues via NIH wide evaluations and portfolio analyses
• Support workshops, lectures, webinars
• Lead or coordinate trans-NIH initiatives
• Facilitate training
• Provide assistance to review
• Provide financial support to grants, contracts, and initiatives
• Coordinate efforts across fed and non-fed entities
• Communicate to OD leadership, broader NIH community, BSSR community, policymakers, etc.
HEALTH ECONOMICS RESEARCH
Clarifying NIH Priorities for Health Economics Research

• Highest Priority Areas:
  – Measure or model the actual or potential impact of specific interventions, approaches, or strategies on health-related behaviors, healthcare utilization, and health outcomes.
  – Understand behavioral, financial, and other factors that influence the implementation, adherence, dissemination, and adoption of medical discoveries into health care.
  – Determine the impact of both financial and non-financial incentives on health-related behaviors, healthcare utilization, and health outcomes.
  – Assess how environmental, social, economic, and other factors affect health status, health-related behaviors, healthcare utilization, health outcomes (including health-related quality of life outcomes), health disparities, and responses to interventions.

Clarifying NIH Priorities for Health Economics Research

• Institute/Center Specific Priorities
  – Analyze organizational influences on the efficiency of the delivery of IC-mission-relevant medical care that are primarily or exclusively focused on healthcare utilization or other health-related outcomes.
  – Assess alternative models of delivering IC-mission-relevant care with a focus on outcomes related to health, including health-related behaviors and healthcare utilization.
  – Measure the economic value of population health and health care delivery relevant to an IC’s mission. Such studies may focus on determining the effects of health status and/or health interventions on broader societal economic outcomes, such as GDP.
  – Broadly describe and quantify the economic impact on society of disease and disability, as well as the impact of IC-specific research and/or evidence-based changes in health practice or health policy.

Clarifying NIH Priorities for Health Economics Research

• Areas Outside the NIH Mission
  
  – Understand individual financial well-being, labor market outcomes, industrial organization, or economic growth without a specific and direct tie to health made within the study aims.
  
  – Examine the financing of healthcare, including the impact of changes in structure or function of the health care marketplace on broad measures of health care cost but not health outcomes.
  
  – Analyze the economics of health professions as they relate to compensation, efficient delivery, or market value, as opposed to health outcomes or access to quality health care.
  
  – Estimate consumer demand for specific interventions, including measures of price elasticity and the effects of healthcare marketing strategies, in which the findings are designed to inform decisions related to profitability, rather than the quality of care or health outcomes.
  
  – Assess the cost and efficiency of healthcare service delivery, in which cost is the primary or major factor by which comparisons are made, without considering clinical outcomes or quality of care.

Relevance to Behavioral and Social Sciences Research

PRECISION MEDICINE INITIATIVE
PMI Proposed Support: FY16

<table>
<thead>
<tr>
<th>Agency</th>
<th>$ Million</th>
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<tbody>
<tr>
<td>NIH</td>
<td>$200</td>
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<tr>
<td></td>
<td>$70</td>
</tr>
<tr>
<td></td>
<td>$130</td>
</tr>
<tr>
<td>Cancer</td>
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<tr>
<td>Cohort</td>
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<tr>
<td>FDA</td>
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<tr>
<td>ONC</td>
<td>$5</td>
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<tr>
<td>TOTAL</td>
<td>$215</td>
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PMI: National Research Cohort

• Will comprise:
  – >1 million U.S. volunteers
  – Patients from Health Provider Organizations (HPOs)
  – New volunteers (Direct-to Volunteer efforts)

• Participants will be:
  – Centrally involved in design, implementation
  – Able to share genomic data, lifestyle information, biological samples – all linked to their electronic health records

• Will forge new model for scientific research that emphasizes:
  – Engaged participants
  – Open, responsible data sharing with privacy protections
PRECISION MEDICINE INITIATIVE COHORT PROGRAM

PMI Cohort Program

October 17, 2015

Funding Opportunities

The Precision Medicine Initiative® (PMI) Cohort Program will partner with others to create this exciting national resource. This page provides links to all active and archived PMI Cohort Program funding opportunities.

<table>
<thead>
<tr>
<th>Title</th>
<th>ID Number</th>
<th>Earliest Submission Date</th>
<th>Application Due Date</th>
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<tbody>
<tr>
<td>Precision Medicine Initiative® Cohort Program Direct Volunteers Pilot Studies (OTA)*</td>
<td>OT-PM-16-001</td>
<td>November 16, 2015</td>
<td>December 22, 2015</td>
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<td>Communication Support for the Precision Medicine Initiative® Research Programs at NIH (OTA)*</td>
<td>OT-PM-16-002</td>
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<td>Precision Medicine Initiative® Cohort Program Biobank (U24)</td>
<td>RFA-PM-16-004</td>
<td>January 4, 2016</td>
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<td>Precision Medicine Initiative® Cohort Program Coordinating Center (U2C)</td>
<td>RFA-PM-16-001</td>
<td>January 17, 2016</td>
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<tr>
<td>Precision Medicine Initiative® Cohort Program Participant Technologies Center (U24)</td>
<td>RFA-PM-16-003</td>
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<tr>
<td>Precision Medicine Initiative® Cohort Program Healthcare Provider Organization Enrollment Centers (UG3/UH3)</td>
<td>RFA-PM-16-002</td>
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* A policy guide for the Other Transactional Authorities (OTA) funding opportunities will be available shortly. Please check this link after Wednesday, November 18, 2015.
Precision Medicine Initiative

Far too many diseases do not have a proven means of prevention or effective treatments. We must gain better insights into the biology of these diseases to make a difference for the millions of Americans who suffer from them. Precision medicine is an emerging approach for disease treatment and prevention that takes into account individual variability in genes, environment, and lifestyle for each person. While significant advances in precision medicine have been made for select cancers, the practice is not currently in use for most diseases. Many efforts are underway to help make precision medicine the norm rather than the exception. To accelerate the pace, President Obama has now unveiled the Precision Medicine Initiative – a bold new enterprise to revolutionize medicine and generate the scientific evidence needed to move the concept of precision medicine into every day clinical practice.
ENVIRONMENTAL INFLUENCES ON CHILD HEALTH OUTCOMES

What happened to the National Children’s Study
Transition for NCS to ECHO

• Children’s Health Act (2000) – national longitudinal study of environmental influences on child health and development

• National Children’s Study ended in 2014
  – Never transitioned from Vanguard to Main Study
  – NAS and ACD reports deemed unfeasible as constructed
  – Vanguard data archived for secondary analysis

• FY15 transition - $144M for:
  – Pediatric Research Using Integrated Sensor Monitoring Systems (PRISMS)
  – Children’s Health and Exposure Analysis Resource (CHEAR)
  – Pediatric Patient-Reported Outcomes in Chronic Disease (PEPR)
  – Extension of Human Placenta Project and Tox21
  – Supplement existing pregnancy, birth, and child cohorts to add or enhance high-dimensional molecular analysis approaches.

• Environmental Influences of Child Health Outcomes (ECHO)
Environmental Influences on Child Health Outcomes (ECHO)

ECHO will support multiple, synergistic, longitudinal studies using existing study populations to investigate environmental exposures — including physical, chemical, biological, social, behavioral, natural and built environments — on child health and development. The studies will focus on four key pediatric outcomes that have a high public health impact:

• Upper and lower airway
• Obesity
• Pre-, peri-, and postnatal outcomes
• Neurodevelopment

The studies will share standardized core data elements to be addressed across all studies are:

• Demographics
• Typical early health and development
• Genetic influences on early childhood health and development
• Environmental factors
• Patient/Person (parent and child)

Reported Outcomes (PROs)

$167M x 7 years

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<tr>
<th>Title</th>
<th>ID Number</th>
<th>Earliest Submission Date</th>
<th>Letter of Intent Due Date</th>
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<td>Clinical Sites for the IDeA States Pediatric Clinical Trials Network (UG1)</td>
<td>RFA-OD-16-001</td>
<td>March 15, 2016</td>
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<td>Data Coordinating and Operations Center for the IDeA States Pediatric Clinical Trials Network (U24)</td>
<td>RFA-OD-16-002</td>
<td>March 15, 2016</td>
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<td>Environmental Influences on Child Health Outcomes: Patient Reported Outcomes Research Resource Center Core (ECHO PRO Core) (U24)</td>
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<td>March 15, 2016</td>
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<td>Environmental influences on Child Health Outcomes (ECHO) Pediatric Cohorts (UG3/UH3)</td>
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<td>Environmental Influences on Child Health Outcomes (ECHO) Data Analysis Center (U24)</td>
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<td>Environmental Influences on Child Health Outcomes (ECHO) Coordinating Center (U2C)</td>
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<td>March 15, 2016</td>
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<td>Limited Competition: Exposure Analysis Services for the Environmental Influences on Children’s Health Outcomes (ECHO) Program (Admin Supplement)</td>
<td>PA-16-046</td>
<td>March 15, 2016</td>
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Need an appropriation to fund new initiatives

NIH BUDGET
National Institutes of Health Funding
1990-2016

Note: The 3.7% Real Annual Growth is based on real compound annual growth between 1971 and 2000. Dollar values are adjusted to 2012 dollars using the Biomedical Research and Development Price Index (BRDPI), http://officeofbudget.od.nih.gov/gbiPriceIndexes.html. Source: NIH Office of Extramural Research and Office of Budget source data (January 8, 2015)
To CR or not CR?

• Current Continuing Resolution expires Dec 11
  – Could get appropriations bill by then
  – Or could get another CR
  – Or could shut down all non-essential services

• Budgets anticipate increase in NIH Funding
  – House $1.1B
  – Senate $2.0B
  – Increases must come from cuts elsewhere
Questions?