

NATIONAL CHILDREN'S STUDY UPDATE

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Director

**National Advisory Child Health and Human
Development Council**

January 22, 2015



National Children's Study

The National Children's Study 2014

An Assessment

Panel on the Design of the National Children's Study and Implications
for the Generalizability of Results

Greg J. Duncan, Nancy J. Kirkendall, and Constance F. Citro, *Editors*

Committee on National Statistics
Division of Behavioral and Social Sciences and Education

Board on Children, Youth, and Families
Institute of Medicine

NATIONAL RESEARCH COUNCIL AND
INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

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NCS Working Group of the ACD

- On June 16th, NIH Director Francis Collins placed the NCS Main Study on hold, to determine the best path forward
- He named a Working Group of the Advisory Committee to the NIH Director to answer key questions about the NCS

NCS Working Group Charge

- To answer questions:
 - Is this study, as currently outlined, actually feasible in the face of significant budget constraints?
 - If yes, how do we move forward to implement necessary changes, including some of those outlined in the NAS report?
 - If no, are there new methods to answer key research questions that are most important to pediatric health today that capitalize on research and technology advances developed in the intervening years since the inception of the study?

NCS Working Group Members



- Russ Altman, MD, PhD, (co-chair)



- Phillip Pizzo, MD, (co-chair)

- Elizabeth Barrett-Connor, MD
- Robert Gibbons, PhD
- Kathy Hudson, PhD
- Renee Jenkins, MD
- Brendan Lee, MD, PhD
- Maureen Lichtveld, MD, MPH
- Marie Lynn Miranda, PhD
- Cheryl Perry, PhD
- Huda Zoghbi, MD

Process to Determine Recommendations

- Met 6 times since with lots of other communications
- Explored a broad range of stakeholder perspectives and a wide range of relevant documents
 - 2008 and 2014 NAS reports
 - Vanguard and Main Study protocols
 - Internal analyses
 - Experts in pediatric research, environmental health, epidemiology, statistical analyses, and longitudinal study design
 - Public comments
- Discussed the current status of the NCS, its strengths and weaknesses, and its overall utility and feasibility

Full Report and Presentation

- See: <http://acd.od.nih.gov/meetings.htm>

Working Group Core Finding

- WG unanimously agreed: “While the overall goals of examining how environmental factors – defined broadly – influence health and development are meritorious and should be a priority for future scientific support, **the NCS, as currently outlined, is not feasible.**”

Recommendations

- Main Study and the Vanguard Study should be closed down
- Vanguard Study data should be archived and available for request by investigators for secondary analysis
- NICHD Program Office should be dissolved
- The topics that reside around the NCS are important and a trans-NIH approach should be pursued, ideally convened and supported by the NIH Office of the Director

Recommendations

- Future studies must incorporate new biological and technical advances
- Future studies are needed to address the interactions between child development and related environmental, behavioral, biological, and societal factors
- Supporting biospecimen collection should permit contemporary tailored investigations and provide flexibility to deploy emerging scientific insights
- Funds should be provided to achieve these goals

Resulting Steps

- NIH accepted the ACD's recommendations and is in the process of closing down the NCS
- David Murray, director of NIH's Office of Disease Prevention, will oversee closing the study
- Steven Hirschfeld has returned, full time, to his role as NICHD Associate Director for Clinical Research
- Jack Moye named NCS Acting Director
- Closure activities are in progress, but no end date yet

Current Status

- Participants in the NCS Vanguard Study received letters thanking them for their participation and explaining that the study is closed
- NCS contractors are working with NIH contracts officers to end activities and turn over work products
- NIH leadership is evaluating how the remaining FY 2015 funds appropriated for NCS can best be spent on research that carries out the original goals of the NCS, as mandated by Congress
- NCS program staff will be reassigned when closeout is complete

Appropriations Language

- “\$165,000,000 shall be for the National Children’s Study (“NCS”) or research related to the Study’s goals and mission, and any funds in excess of the estimated need shall be transferred to and merged with the accounts for the various Institutes and Centers to support activity related to the goals and objectives of the NCS...NIH shall submit a spend plan on the NCS’s next phase ... not later than 90 days after the date of enactment of this Act...”

Now it's your turn...



Comments, questions?