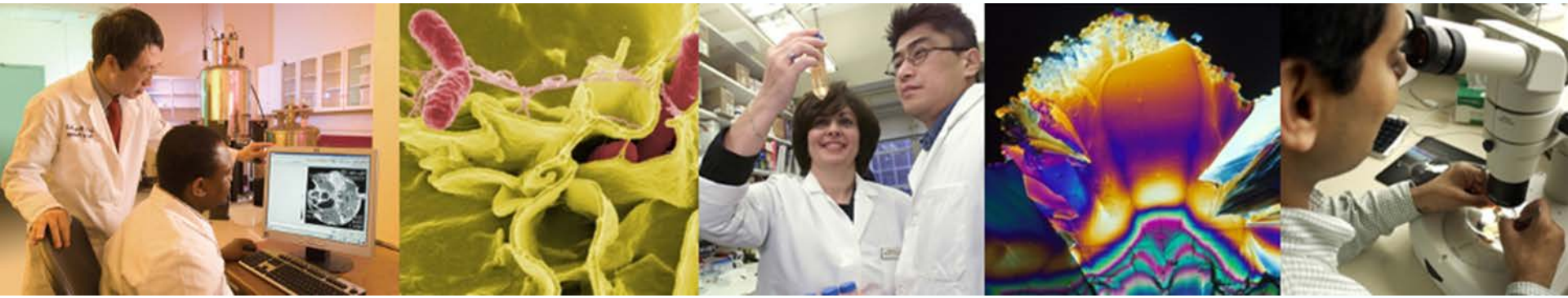
National Children's Study:
Reallocation of FY15 Funds

Council of Councils

January 30, 2015



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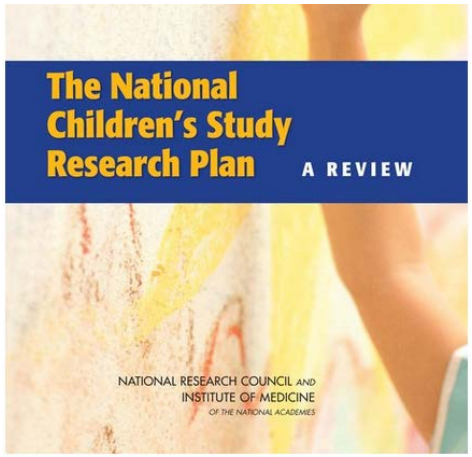
History of the National Children's Study (NCS)

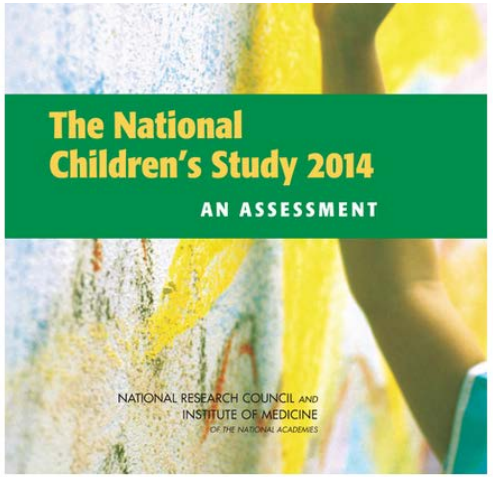
- Children's Health Act of 2000
  - Directed NICHD to establish a consortium to:
    - Plan, develop, and implement a prospective cohort study to evaluate the effects of chronic and intermittent exposures on child health and human development
    - Investigate basic mechanisms of developmental disorders and environmental factors that influence health and developmental processes
- NCS Study
  - Vanguard Study: Pilot Launched in 2009
  - Main Study: Not yet initiated

Previous IOM Reviews of the NCS

It is clear from our review that the NCS offers not only enormous potential, but also a large number of conceptual, methodological, and administrative challenges.



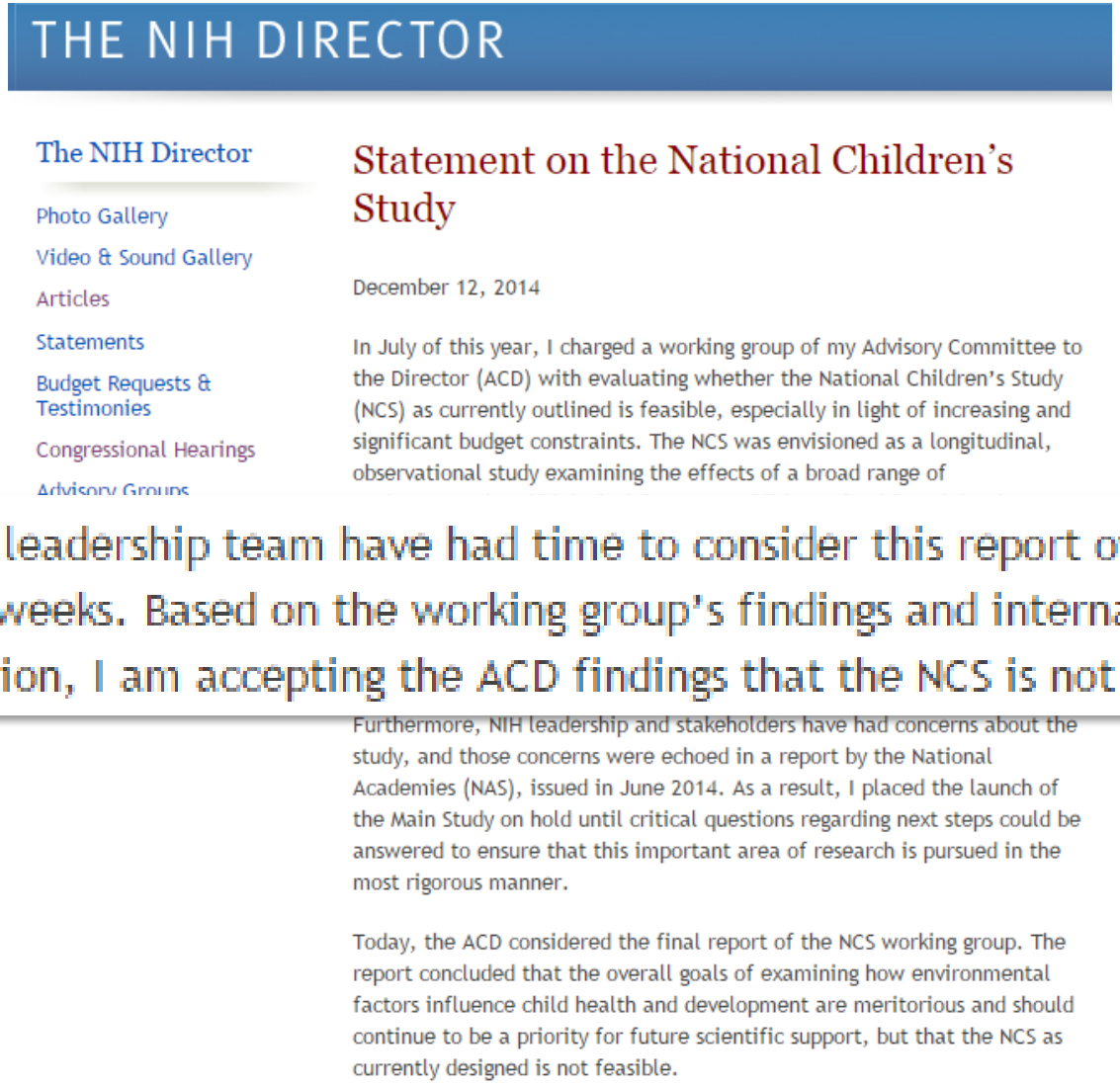
The NCS Main Study offers enormous potential, but it also presents a large number of conceptual, methodological, and administrative challenges.



ACD Working Group Review of NCS

- Persistent concerns led to the study being put on hold and an evaluation by an ACD working group
- Working Group Finding:
  - "while the overall goals [of examining how environmental factors influence health and development] are meritorious and should be a priority for future scientific support, **the NCS, as currently outlined, is not feasible**."
- Working Group Recommendation:
  - NIH should "**champion and support new study designs, informed by advances in technology and basic and applied research**…that could make the original and overall goals of the NCS more achievable, feasible and affordable."

NCS Discontinued



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Statement on the National Children's Study

December 12, 2014

In July of this year, I charged a working group of my Advisory Committee to the Director (ACD) with evaluating whether the National Children's Study (NCS) as currently outlined is feasible, especially in light of increasing and significant budget constraints. The NCS was envisioned as a longitudinal, observational study examining the effects of a broad range of

I and my leadership team have had time to consider this report over the last few weeks. Based on the working group's findings and internal deliberation, I am accepting the ACD findings that the NCS is not feasible.

Furthermore, NIH leadership and stakeholders have had concerns about the study, and those concerns were echoed in a report by the National Academies (NAS), issued in June 2014. As a result, I placed the launch of the Main Study on hold until critical questions regarding next steps could be answered to ensure that this important area of research is pursued in the most rigorous manner.

Today, the ACD considered the final report of the NCS working group. The report concluded that the overall goals of examining how environmental factors influence child health and development are meritorious and should continue to be a priority for future scientific support, but that the NCS as currently designed is not feasible.

FY15 Appropriations

- $165M Appropriated for NCS in FY15 Appropriations
- Bill and Report Language direct NIH to maintain the mission and goals of the NCS, with flexibility on how to carry this out
- Redirection of NCS resources- challenges and opportunities

Proposed Redirection of NCS Funds

- Remain true to the original intent of the NCS – address questions at the intersection between pediatric health and the environment
- More focused effort that stresses the engagement of underrepresented communities
- Three Initiatives:
  - **Initiative 1**: Develop tools that would enhance studies of environmental influences of pediatric diseases
  - **Initiative 2**: Study the influence of environment on *in utero* development with the goal of identifying the "seeds" of future diseases and conditions
  - **Initiative 3**: Expand examination of environmental influences on later child development by leveraging extant programs

Rationale

- Need for technological advances, including sensors and related technologies, to enhance data collection, specifically that of environmental exposures
  - NCS ACD Working Group Report
  - NIBIB Strategic Plan
  - 2014 IOM Review/EPA Workshop
- Dearth of understanding around environmental effects on in utero development, especially long-term health effects related to placental development and function
  - NICHD Scientific Vision
  - 2014 IOM Review/EPA Workshop

Proposed Plan: Initiative 1

- **Core Effort** – Develop tools that would enhance studies of environmental influences of pediatric diseases
  - (NEW) Biosensor Based Integrated Health Monitoring Systems for Environmentally and Behaviorally Related Pediatric Health Problems
    - Wearable (including *in utero*) and static sensors to provide data on exposure factors, both environmental and behavioral
  - (NEW) Children's Health Exposure Analysis Resource
    - Network providing an integrated infrastructure for standardized characterization of multiple environmental and genetic factors as determinants of pediatric health

Proposed Plan: Initiative 1 (cont'd)

- **Core Effort** – Develop tools that would enhance studies of environmental influences of pediatric diseases
  - (Expand Extant Program) Clinical Validation of Patient Reported Outcomes (PROMIS) Items Banks in Children
    - Validate PROMIS measures for children (e.g., obesity, asthma, juvenile arthritis) with inclusion of environmental components

Proposed Plan: Initiative 2

- Study the influence of environment on *in utero* development with the goal of identifying the "seeds" of future diseases and conditions
  - (Expand Extant Program) Tox21 Developmental Toxicity Program
    - Comprehensive testing program of the Tox21 10,000 chemical collection on developmental pathways and cellular phenotypes
  - (Expand Extant Program) Human Placenta Project
    - Develop methods to assess environmental influences on human placental function and fetal development in real time

Proposed Plan: Initiative 3

- Expand examination of environmental influences on later child development by leveraging extant programs
  - (Expand Extant Program) Supplemental Support for Existing Children's Environmental Health Cohorts
    - Add proteomic, metabolomics, and epigenetic analyses to well-characterized cohorts, and enhance GxE interaction studies




NIH...

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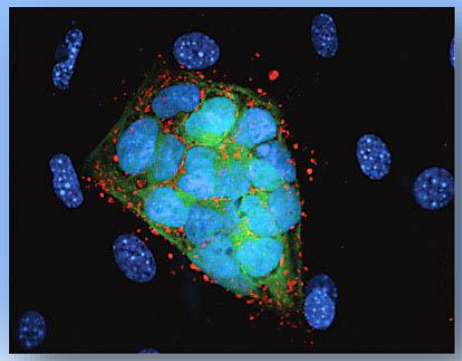
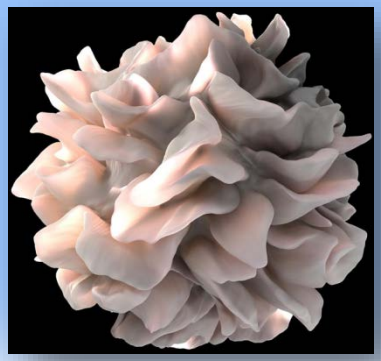
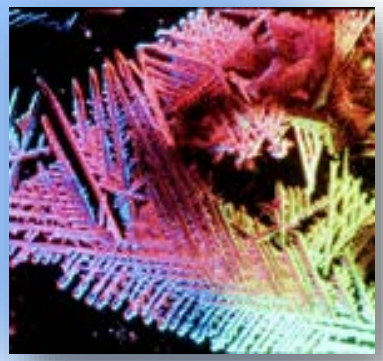
Turning Discovery Into Health

Current NIH Environmental Pediatric Research Portfolio