



ACADEMIC
PEDIATRIC
ASSOCIATION

AMERICAN
PEDIATRIC
SOCIETY

ASSOCIATION OF MEDICAL
SCHOOL PEDIATRIC
DEPARTMENT CHAIRS

SOCIETY FOR
PEDIATRIC
RESEARCH

October 31, 2014

Russ Altman, MD, PhD
Co-Chair
National Children's Study Working Group
Advisory Committee to the Director
National Institutes of Health
One Center Drive, Room 114
Bethesda, Maryland 20892-0147

Phillip Pizzo, MD
Co-Chair
National Children's Study Working Group
Advisory Committee to the Director
National Institutes of Health
One Center Drive, Room 114
Bethesda, Maryland 20892-0147

Dear Drs. Altman and Pizzo:

As organizations representing pediatric clinicians, researchers, and educators, we write to provide the perspectives of our organizations on the process to determine the future of the National Children's Study. We represent the Academic Pediatric Association, the American Pediatric Society, the Association of Medical School Pediatric Department Chairs, and the Society for Pediatric Research, groups that collectively advocate as the Pediatric Policy Council for public investments in child health and well-being, including our nation's pediatric research.

Fourteen years ago this month, the *Children's Health Act of 2000* was signed into law, authorizing the creation of the National Children's Study (NCS). The law was passed with significant support from the pediatric community. It called for a "prospective cohort study, from birth to adulthood, to evaluate the effect of both chronic and intermittent exposures on child health and human development." The study was modeled as an ambitious and unprecedented effort to make new discoveries regarding environmental influences and the health of children. The goals of the study were, and continue to be, crucial for child health.

Today, the main arm of the NCS has yet to be initiated. Years of planning and pilot testing identified obstacles to conducting the study as originally outlined, and efforts to overcome these obstacles have raised questions regarding whether the study would produce complete and generalizable data. A report released earlier this year by the National Academies of Sciences (NAS) strongly supported the goals of the NCS but raised serious concerns about study methodology and management.

There is general agreement within the memberships of our organizations—which represent a broad swath of the pediatric research and larger pediatric communities—that while the NCS faces challenging methodological concerns, the study would have the potential to greatly benefit child health if those challenges could be overcome and the study was appropriately resourced. However, views on the feasibility of overcoming these challenges in an environment of constrained resources vary widely.

The core of your working group's charge is to determine whether the NCS is "feasible, as currently outlined, especially in light of increased and significant budget constraints." While our organizations do not collectively offer an answer to that fundamental question, we do agree that it is the correct question to be considered, in a careful and comprehensive manner. We urge the working group to review all available information and to make a determination that is in the best interests of the health of the nation's children.

We strongly believe, however, that now is the time for a decisive act in the history of the NCS. We can no longer afford to advocate each year for significant public resources to be committed to an effort that continues to be the subject of such uncertainty. The NIH and the pediatric community need a clear path forward.

If your working group determines that the NCS is feasible, as described in your charge, we implore you to outline a plan to quickly address needed changes that will allow the main arm of the study to begin with appropriate funding as soon as possible. Further delays in the start of the main study will jeopardize the remaining public and congressional support for the program.

If, on the other hand, your group determines that the study as currently formulated is not feasible, we urge you to move forward with an equally ambitious replacement pediatric study program that would fill the gaps left by the elimination of the NCS. Even if the NCS does not go forward, its goals remain vitally important for child health and must be addressed through development of strong methodologies and continued commitment of similar levels of resources. We would also encourage the working group to make recommendations to the NIH regarding how to make use of the work already completed on the NCS so that the substantial investments that have been made are not lost.

There is no doubt that we must implement a highly meritorious study program that addresses important pediatric and environmental health issues using state of the art technologies and methodologies.

Thank you for agreeing to lead this important effort for child health.

Sincerely,

Academic Pediatric Association
American Pediatric Society
Association of Medical School Pediatric Department Chairs
Society for Pediatric Research

cc. Francis Collins, MD, Director, National Institutes of Health
Alan Guttmacher, MD, Director, National Institute of Child Health and Human Development

Members of the National Children's Study Working Group:

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