Dear Colleague,

The inclusion of children in human subjects’ research is essential to ensure that children benefit from important scientific advances, as well as for understanding how diseases develop and persist later into adulthood. While the National Institutes of Health (NIH) formally encourages the inclusion of children as research participants in its clinical trials, we are concerned that the NIH is not adequately tracking whether children are appropriately included in all of its clinical trials relevant to child health.

In 1993, Congress required that the NIH publish formal policies requiring the inclusion of women, minorities and children in NIH research. Since the enactment of these policies, the NIH has tracked the inclusion of women and minorities in NIH-funded research by collecting data on the race and gender of enrollees in clinical trials, but has not systematically tracked the ages of those enrolled in trials.

While institutes and centers across the NIH do conduct specific pediatric research, the current NIH grant application process leaves grant reviewers little information with which to differentiate between meaningful pediatric representation and negligible inclusion of 18 to 20 year olds. In addition, the current mechanisms the NIH uses to categorize research cannot determine whether adult-focused research inappropriately excludes children or whether pediatric-specific research appropriately includes children from typically underrepresented age groups such as neonates and infants. We are concerned that this lack of tracking leaves the NIH unable to answer questions about whether children are appropriately included in trials pertinent to them. In the absence of better data, the potential overrepresentation of older adolescents (i.e. ages 18-21) and underrepresentation of younger children could continue without opportunity for public comment or oversight.

Investment in child health research is a vitally important national priority and the absence of data is not an answer. In order to ensure that specific investigator data inclusion and reporting requirements as well as reviewer mechanisms remain as comprehensive and transparent as possible, we invite you to join us in sending the attached letter to NIH Director Francis Collins requesting information on the NIH process to monitor implementation of its pediatric inclusion policy.

We hope you will work with us to enhance pediatric health research findings and ensure that children are appropriately included in all NIH clinical trials that have relevance to child health and development. For more information, or to sign on to the letter, please contact Araceli Gutierrez in Representative Roybal-Allard’s office at Araceli.Gutierrez@mail.house.gov or Chris Cooper in Representative Joyce’s office at Chris.Cooper@mail.house.gov.

Sincerely,

Lucille Roybal-Allard  
Member of Congress

Michael Simpson  
Member of Congress

David P. Joyce  
Member of Congress
Dear Dr. Collins:

As you know, NIH policy requires that children be included in NIH-sponsored clinical trials unless there is reason to exclude them. While institutes and centers across the National Institutes of Health (NIH) do in fact conduct specific pediatric research, we are concerned that the NIH is not adequately tracking whether children are appropriately included in all of its clinical trials relevant to child health.

In 1993, Congress required the inclusion of women and minorities in NIH research (Pub. L. 103-43, 42 U.S.C. 289a-2), but no such provision existed for children. After advocacy by the American Academy of Pediatrics and directives from the House and Senate in FY1996 appropriations reports, the NIH published a formal policy requiring the inclusion of children in research. Since that time the NIH has tracked the inclusion of women and minorities in NIH-funded research by gathering data on the sex/gender and race/ethnicity of enrollees in clinical trials, but has not systematically tracked the ages of those enrolled in trials, even though this information is readily available.

Specifically, the NIH grant application process collects information about whether or not a proposed research project would include any children under the age of 21, but leaves grant reviewers little information with which to differentiate between meaningful pediatric representation and negligible inclusion of 18 to 20 year olds. In addition, mechanisms the NIH uses to categorize research, such as the Research, Condition, and Disease Categorization (RCDC) system, are not designed to answer questions about trial enrollment. While RCDC classifies some research as “pediatric” in nature, RCDC cannot determine whether adult-focused research inappropriately excludes children or whether pediatric-specific research appropriately includes children from typically underrepresented age groups such as neonates and infants.

We are concerned that this lack of tracking leaves the NIH unable to answer questions about whether children are appropriately included in trials pertinent to them. For that reason we would request that you provide us with the following information:

1. Please describe the process by which the NIH monitors the implementation of its pediatric inclusion policy. In particular, how does the NIH determine whether grant proposals appropriately incorporate children into their research plans?
2. After an award is made, how does the NIH track whether children are adequately enrolled in trials that may benefit the pediatric population?
3. Finally, please describe why the NIH does not collect information on trial enrollment by pediatric age group as it does for sex/gender and race/ethnicity.

Investment in child health research is a vitally important national priority, not only to guarantee that children benefit from important scientific advances, but also to better understanding how chronic diseases develop and persist later into adulthood. We look forward to working with you to ensure that children are appropriately included in all NIH clinical trials that have relevance to child health and development.

Thank you for your attention to this important issue.

Sincerely,