

June 20, 2018

RE: EPA Proposed Rule “Strengthening Transparency in Regulatory Science”

Submitted online via *Regulations.gov* to docket EPA-HQ-OA-2018-0259

These comments are submitted on behalf of the undersigned scientists. The co-signers’ institutional affiliations are included for identification purposes only and do not imply institutional endorsement or support.

We are current and former principal investigators researching children’s environmental health through the NIEHS/EPA Children’s Environmental Health and Disease Prevention Research Centers Program (Children’s Centers).¹ We appreciate the opportunity to provide comments on the EPA Proposed Rule “Strengthening Transparency in Regulatory Science.”² We are concerned that the proposed rule will adversely affect EPA’s ability to use science in decision-making and ultimately negatively influence protections for children’s health.

Science is at the core of EPA’s mission, and research from Children’s Centers contributes significantly to the foundation of knowledge that informs and supports the Agency’s ability to protect the public. The National Academies of Sciences (NAS) highlighted that “Children’s Centers have led to an improved understanding of the environmental impacts on child health and development.”³ Children’s Centers research identified the critical contributions of environmental exposures to asthma, obesity, ADHD, cancer, autism and other childhood illnesses. This research has led to new detection, treatment and prevention strategies for such diseases, often with a focus on vulnerable and underserved communities, benefiting children’s health. For example, research from Children’s Centers informed EPA standards for cleaner air, which improved the quality of life for children.⁴

Collectively, we have research data from thousands of participants across the country, including some of our most vulnerable populations--children and women in communities of color. To not use or consider studies that do not comply with the proposed rule is inconsistent with scientific principles and evidence-based policy, and would put the public at risk from toxic chemicals.

Institutional Review Boards (IRBs) require that we protect the privacy and confidentiality of our participants— but IRB requirements conflict with this rule’s mandate to publicly reveal individual-level data. Data masking, coding and de-identification techniques have limitations because re-identification of participants is still possible using external information available online and through other sources.⁵

¹ NIEHS. NIEHS/EPA Children’s Environmental Health and Disease Prevention Research Centers. Oct 30, 2017. Available: <https://www.niehs.nih.gov/research/supported/centers/prevention/index.cfm>

² Federal Register Vol 83, No 83. Monday, April 30, 2018. Pp 18768-18774

³ National Academies of Sciences, Engineering, and Medicine. 2017. A Review of the Environmental Protection Agency’s Science to Achieve Results Research Program. Washington, DC: The National Academies Press.

⁴ NIEHS and EPA. NIEHS/EPA Children’s Environmental Health and Disease Prevention Research Centers Impact Report: Protecting Children’s Health Where They Live, Learn and Play. Oct 2017. Available: https://www.epa.gov/sites/production/files/2017-10/documents/niehs_epa_childrens_centers_impact_report_2017_0.pdf

⁵ See, for example, the extensive discussion on re-identification here: National Academies of Sciences, Engineering, and Medicine. 2016. Principles and obstacles for sharing data from environmental health research: Workshop summary. Washington, DC: The National Academies Press. doi: 10.17226/21703.

Additionally, de-identification methods can degrade the accuracy of data for multi-variate statistical analysis or data mining, potentially masking important relationships, such as racial differences in outcomes.⁶

Further, experience with re-analysis shows that simply making data available is insufficient; the participation of the original researchers is often required because of their unique expertise in the design, collection and analysis, especially for large or complex datasets.⁷ Such participation could be a substantial time and resource burden on researchers.

We are especially concerned that the rule inappropriately codifies specific data analysis approaches (such as dose-response modeling) and other scientific decisions that should be made based on empirical considerations. This will hinder scientific inquiry and lead to inaccurate results. As scientists, we value open science—but the mandates laid out in this rule will not improve data sharing, replicability, or transparency. Instead, implementation of this rule—especially retroactively—could lead to EPA excluding numerous relevant studies from policy decisions, to the ultimate detriment of children’s health. We urge EPA not to move forward with this proposed rule.

Please do not hesitate to contact us with any questions regarding these comments.

Sincerely,

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⁶ Barth-Jones, D. C. 2014. *Challenges associated with data-sharing: HIPAA deidentification*. Presentation at the workshop Principles and Obstacles for Sharing Data from Environmental Health Research, Washington, DC. Available: http://www.nationalacademies.org/hmd/~media/Files/Activity%20Files/Environment/EnvironmentalHealthRT/2014-03/Daniel-Barth-Jones_March2014.pdf

⁷ National Research Council. 2002. *Access to Research Data in the 21st Century: An Ongoing Dialogue Among Interested Parties: Report of a Workshop*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/10302>. Pg. 22.

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