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**Ex Officio**

*Elisa A. Hurley, PhD  
Executive Director*

August 1, 2018

Submitted electronically at

[www.regulations.gov](http://www.regulations.gov)

The Honorable Andrew Wheeler

Acting Administrator

Environmental Protection Agency

1200 Pennsylvania Avenue NW

Washington, DC 20460

RE: Docket No. EPA-HQ-OA-2018-0259, "Strengthening Transparency in Regulatory Science" (83 *Federal Register* 18768)

Dear Acting Administrator Wheeler,

Public Responsibility in Medicine and Research (PRIM&R) appreciates the opportunity to comment on the Environmental Protection Agency (EPA)'s proposed rule "Strengthening Transparency in Regulatory Science" published April 30, 2018.

PRIM&R is a nonpartisan nonprofit organization dedicated to advancing the highest ethical standards in the conduct of research that advances human health and well-being. Since 1974, PRIM&R has served as a professional home and trusted thought leader for the research protections community, in particular, members and staff of the human research protection programs and institutional review boards who support responsible science by protecting the rights and welfare of research participants. The constituents we serve work to protect research participants' privacy, maintain the confidentiality of participant data, and recognize and respect participant contributions to scientific advancement.

We have serious concerns about the proposed rule. First, we believe that, far from enhancing transparency, the proposed rule arbitrarily and unnecessarily restricts access to and use of rigorous science in environmental policymaking, to the detriment of the public's health and trust in the regulatory process. Second, we believe the proposed

rule does not respect the contributions of human research participants. We thus urge the EPA to withdraw the proposed rule immediately. We expand on each of our concerns below.

I. The proposed rule does not enhance transparency in science

The proposed rule's appeal to transparency in science is misleading. Support of transparency, reproducibility, and open science—values to which PRIM&R is committed—should not be equated with the view that data that are not publicly available are unreliable and useless. Yet that is the very assumption that undergirds the proposed rule.

The proposed rule would endanger the health of all people in the United States without *any* evidence that the science the EPA reviewed and relied on in the past to protect the public's health is invalid. There are legitimate scientific and ethical reasons why data underlying a study's findings are not readily publicly available, including reasons related to the technology available at the time of data collection, outdated formats in which data sets from older studies are stored, and promises made to protect the privacy of individual study participants. None of these are attempts to keep scientific data "secret." For example, data from the 1993 "Six Cities" study that established an association between air pollution and mortality could not be made public in part because study participants were promised at the time of enrollment that their individual information would not be shared.<sup>1</sup> The proposed rule would disqualify studies such as this and other existing high-quality, peer-reviewed science from use in policymaking. Doing so will prevent the EPA from basing environmental policy on the best available scientific evidence and thus make it more difficult for the agency to make decisions that adequately protect the public's health, as its mission requires.

Furthermore, the proposed rule undermines its claim of promoting transparency within the EPA regarding environmental policymaking. The proposed rule does not say that a scientist has to make her study data publicly available, if the EPA is to consider using that study to inform policy. Rather, it says that her study *will not be considered* as a basis for EPA decisionmaking. The proposed rule requires no transparency regarding when and under what circumstances the EPA might decide unilaterally that a rigorous, independently validated, peer-reviewed study cannot be used as a basis for regulatory policymaking, solely on the grounds that its underlying data are not publicly available. Indeed, under the proposed rule, the public would never know that a decision not to use a particular study

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<sup>1</sup> Dockery, D.W., Pope, C.A., Xu, X., Spengler, J.D., Ware, J.H., Fay, M.E., Ferris, Jr., B.G., Speizer, F.E. An Association Between Air Pollution and Mortality in Six U.S. Cities. *N Engl J Med.* 1993 329:1753-1759. <https://www.nejm.org/doi/full/10.1056/NEJM199312093292401>.

had been made. In that sense, the proposed rule will foster a *lack* of transparency about EPA decisions and the science that serves as the basis for its regulatory policy.

## II. The proposed rule fails to respect human research participants

The proposed rule will also result in the EPA disregarding the contributions of the human beings who take part in public health research and potentially violating their privacy.

As written, the proposed rule is intended to be retroactive and prohibit the EPA from considering studies completed prior to the effective date of the rule for which the data are not publicly available. This entails rejecting the contributions of thousands of individuals who—for the benefit of future generations and to advance the public good—agreed to take part in research. Many important public health and environmental studies have taken place after one-time events and natural disasters, such as Hurricane Katrina or the Deepwater Horizon oil spill. Individuals who live through such events and agree to participate in research so that we might learn about these events' impact on human health deserve to have their contributions recognized without compromising their privacy; the proposed rule fails to respect this obligation. Replicating these studies would be ethically impossible, as doing so would require intentionally exposing people to harmful contaminants or recreating one-time public health disasters. Disqualifying such studies, as the rule proposes to do, means losing valuable public health knowledge, for instance, on the effects of environmental pollutants on human health. *A priori* limitation on use of previously collected data disrespects and dishonors the contributions of those who agreed to participate in such research.

Furthermore, the proposed rule does not acknowledge that large scale public health and environmental studies of the sort that inform EPA policy typically collect sensitive health data and other information from individuals, sometimes over a long period of time, in an effort to track the influence of environmental factors on health and well-being. People who agree to be in such studies are assured that their information will be kept confidential and their privacy protected. In proposing to redact private information, the proposed rule fails to acknowledge the enormously burdensome and costly complexities involved in redacting such information in a way that both protects individuals' privacy and ensures that the data is still useful for future analysis.

For instance, the proposed rule will undercut the EPA's ability to understand how exposure to pollutants affects vulnerable populations, including economically disadvantaged communities, the young, and the elderly. For these types of studies, redacting demographic information such as age or location would undermine the data's usefulness for determining the impact of pollution on health. On the other hand, making such information available,

even when other personal information is redacted, leaves it far too easy to identify participants, given the characteristics of the communities being studied. The proposed rule will result, then, in either violating research participants' privacy or making their data useless. Either way, the proposed rule fails to respect human research participants and does a disservice to the communities that are most likely to be vulnerable to environmental pollutants and hazards.

As another example of how the rule fails to recognize participant contributions, consider longitudinal observational field work or participatory-action research conducted in neighborhoods or communities with a high incidence of diseases like asthma or cancer.<sup>2</sup> Much of this research involves researchers generating data sets comprising interview recordings and transcripts from participants who have agreed to donate sometimes significant amounts of time to the research. In the context of these types of research, it would be unethical to share even heavily redacted "raw" data, because part of what researchers offer people when interviewing them is complete confidentiality, which is central to building up the trust that enables valuable data collection in the first place. Research participants may agree to provide their information on the condition that it remain confidential, out of fear of retaliation for participating in a study that may negatively impact the interests of powerful parties (i.e., landlords, employers, industry leaders, etc.). The proposed rule does not take these facts into account. It would instead impose a blanket disqualification on the use of such research findings in EPA decisionmaking regarding environmental factors that affect human health.

Certainly, across a number of disciplines, the scientific community is already using a range of mechanisms to meaningfully share study data and ensure participant privacy protections; however, these mechanisms are not appropriate for all types of research. Moreover, executing these mechanisms can be resource-intensive. The proposed rule fails to recognize that the research needed to inform EPA's decisionmaking is heterogeneous, and that for some types of research, making underlying data available is neither feasible nor ethical.

Thank you again for the opportunity to comment. We urge the EPA in the strongest terms not to move forward with the proposed rule. By promoting an opaque and arbitrary evidence base for policymaking, the proposed rule will erode public trust in the EPA and its regulatory processes. We urge the EPA to withdraw the rule and opt instead for protecting

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<sup>2</sup> Cook, W.K, Integrating Research and Action: A Systematic Review of Community-based Participatory Research To Address Health Disparities In Environmental and Occupational Health in the United States. *J Epidemiol Community Health*. 2008 Aug; 62(8): 668-676. <https://jech.bmj.com/content/62/8/668.long>.

the public's health with the best available science and respecting the contributions of the human research participants who make that science possible. My PRIM&R colleagues and I are available to discuss our comments further, should that be of interest. Please feel free to contact me at 617.303.1872 or [ehurley@primr.org](mailto:ehurley@primr.org).

Respectfully submitted,

A handwritten signature in black ink that reads "Elisa A. Hurley". The signature is written in a cursive style with a long, sweeping tail on the letter "y".

Elisa A. Hurley, PhD  
Executive Director

cc: PRIM&R Public Policy Committee, PRIM&R Board of Directors