August 16, 2018

The Honorable Andrew Wheeler
Acting Administrator
Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, DC 20460

RE: Strengthening Transparency in Regulatory Science, Proposed Rule published April 30, 2018; Agency Docket Numbers EPA-HQ-OA-2018-0259; FRL-9977-40-ORD; FRL-9978-31-ORD

Dear Administrator Wheeler:

As leaders at the University of Washington with particular expertise in environmental policy, we are writing to comment on the proposed rule on "Strengthening Transparency in Regulatory Science." The University of Washington is a leading research-intensive institution of higher learning, and is proud to conduct scientific research that has lasting impact and can contribute to the public good. Our institution has a history of conducting research that informs regulatory decision-making, termed as "pivotal regulatory science" in this proposed rule. We find that the proposed rule places substantial and unreasonable restrictions on what research EPA can consider in its decision-making for regulating important environmental factors including air pollution, water pollution, toxic chemicals, and agents with climate impacts. This rule would negate the use, application, and impact of existing and future valid research and hence threaten public health. The University of Washington recommends that the EPA withdraw this proposed rule, for the reasons discussed below.

The proposed rule would limit consideration of science in decision-making in a manner that is unjustified and arbitrary, and would lead to inadequate regulatory protections, inconsistent with federal law. Existing law and precedent dictates that the EPA take action based on the weight of scientific evidence even in the face of some uncertainty. This requires that the agency considers all available scientific evidence in its decision-making and not make arbitrary exclusions of research. The principal focus of the proposed rule is to require full access to original data for scientific studies in order for those studies to be used for regulatory decision-making. While the preamble to the rule indicates that this could be done while maintaining the protection of privacy and confidentiality of research participants, the proposed rule does not include specific provisions to make these protections possible. A substantial amount of pivotal regulatory science includes epidemiological research in which the maintenance of privacy and confidentiality of research participants is essential to conducting the research. As examples, we can note two papers from the University of Washington that involved studies that ensure confidentiality of the participants (Miller KA et al, Long-term exposure to fine particulate matter air pollution and cardiovascular events in women. New England Journal of Medicine 2007; 356:447-58; and Kaufman JD et al, Association between air pollution and coronary artery calcification within six metropolitan areas in the USA [The Multi-Ethnic Study of Atherosclerosis and Air Pollution]: a longitudinal cohort study. The Lancet 2016; 388:696-704). Both studies contain dose response data and models as anticipated in the proposed rule, and for which the proposed rule creates an

expectation that data required to replicate the analysis be made available. In each case, the underlying studies are conducted with strict rules under the auspices of the National Institutes of Health (National Heart, Lung, and Blood Institute), that preclude any potential identification of subject identity or confidential information. The NIH and the approving institutional review boards would not permit release of the data in a way that would adhere to the letter of the rule. It is possible that limited datasets could be created for replication analysis that would protect participant identity and confidential information, but funds are not available to create these datasets, and the rule is not clear that such a limited dataset would be acceptable. As a result, the rule would lead to arbitrary exclusion of pertinent scientific evidence.

Existing processes for evaluating the quality of scientific data are adequate. The current state of scientific practice permits decision-makers to consider all peer-reviewed science and make decisions based on the weight of evidence. The proposed rule suggests that there is a crisis to be addressed, in that scientific data to support environmental decision-making cannot be replicated. The rule cites examples primarily related to replication issues in the pharmaceutical industry. Such issues are not documented to be prevalent in the environmental research area. The studies which are frequently noted to be problematic since raw data was not available for replication—the Harvard Six Cities Study and American Cancer Society CPS II cohorts studies which demonstrated the effect of particulate matter on cardiovascular disease—have not only been independently confirmed by reanalysis by the independent Health Effects Institute, but also replicated by dozens of subsequent research studies [see the two papers cited above as well as Hoek et al Environmental Health 213; 12:43]. The scientific peer review process, along with the ability to weigh the entire extent of published data, is entirely adequate to determine the state of the evidence regarding environmental effects of agents considered for regulation. The solution to an inadequate research database for regulatory decision-making is not to exclude research from consideration as proposed in this rule, but rather to provide funding and incentives for more and better research to answer important environmental questions. The proposed rule cites policies from several leading journals as justifying the need for the proposed rule, however, the editors of all of those journals (Science, Nature, PLOS, PNAS, and Cell) wrote to indicate this rule is not justified.

We recommend that the EPA withdraw the proposed rule and focus on: 1) implementing existing initiatives and guidelines for improving data sharing and transparency at federal agencies; and 2) encouraging development of high-quality research that can be used to provide pivotal regulatory science, through funding of important research topics and through processes to establish datasets which can be used for replication of key findings.

Sincerely,

Hilary Godwin, PhD Dean and Professor UW School of Public Health	Lisa J. Graumlich, PhD Mary Laird Wood Professor & Dean UW College of the Environment	Joel Kaufman, MD, MPH Acting Associate Dean and Professor UW School of Public Health