American Society for Investigative Pathology
Investigating the Pathogenesis of Disease

WILLIAM B. COLEMAN, PHD
EXECUTIVE OFFICER
1801 Rockville Pike, Suite 350, Rockville, MD 20852 (USA)
Tel: 240-283-9700 • Fax: 301-984-4047 • Email: asip@asip.org • www.asip.org

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Andrew Wheeler
Interim Administrator
U.S. Environmental Protection Agency
EPA Docket Center, EPA-HQ-OA-2018-0259
Mail Code 28221T
1200 Pennsylvania Ave., NW
Washington D.C., 20460

Re: Docket No. EPA-HQ-OA-2018-0259

Comments submitted electronically to the docket at www.regulations.gov

Dear Administrator Wheeler:

Thank you for the opportunity to provide these written comments on behalf of the *American Society for Investigative Pathology* (ASIP) to the request for comments in Docket No. EPA-HQ-OA-2018-0259. ASIP is a nonprofit educational 501(c)(3) organization primarily representing the academic pathology research community. We are a society of biomedical scientists who investigate disease, linking the presentation of disease in the whole organism to its fundamental cellular and molecular mechanisms. Our members use a variety of structural, functional, and genetic techniques, seeking to ultimately apply research findings to the diagnosis and treatment of patients. Our society represents approximately 1,000 physicians and doctoral scientists who perform or are involved with pathology research in academic medicine, government, and private industry.

While in the guise of "strengthening transparency in regulatory science," the ASIP is deeply concerned that the potential adoption of the regulations would allow the government to discount or ignore vital scientific research and to rescind current regulations and environmental pollution goals based on previous studies that are scientifically sound but do not meet the new proposed transparency standards. The ASIP supports the following general principles: research rigor and reproducibility, importance of identifying assumptions used in experimental design and data analysis, transparency in regulatory science, and the critical role of independent peer review without real or apparent conflicts of interest. **The merit and contribution of scientific studies should continue to be judged on the strength of the research design, execution, data analysis, and peer review of the research study.**

We have reviewed the comment letter submitted by *The Endocrine Society* and the joint comment letter submitted by the *Association of American Medical Colleges*, *Association of American Universities*, *Association of Public and Land-grant Universities*, and *Council on Governmental Relations*. The ASIP wholeheartedly endorses the views expressed in both letters and joins all these parties and others in urging the EPA to promptly rescind this proposed rule and to open a meaningful discussion on these issues with the scientific community.

We find that EPA's NPRM is not sufficiently transparent as it does not propose standards by which past, current, and future research will be evaluated. Nor is there transparency as to whether this

NPRM would pose an increased administrative burden upon researchers. Such transparency from EPA is imperative as researchers should understand how the NPRM will be put into practice in order that they may design, carry out, and analyze their future research in compliance with the proposed EPA standards. EPA should also outline the process by which it will determine that a research project meets the transparency standards; this should include specifying who will review the project and the criteria to be applied.

The ASIP believes that research abiding by the policies of federal funding agencies or adhering to guidelines established by high-quality peer-reviewed journals should be considered sufficiently publicly available for validation and analysis. The proposed EPA data standards should not be used to disregard regulations based on previously collected data from peer-reviewed scientific studies unless new data from peer-reviewed scientific studies call those earlier studies into question. It would be a disservice to research participants if the research results garnered from their past or current participation were disregarded. In addition, replication of existing studies to comply with new regulations would pose a significant financial and administrative burden.

EPA must provide focused, detailed attention to the complicated interface between human subject research protections and these proposed regulations. Scientific data may not be available to the public based on valid, reasonable and ethical reasons. Research adhering to the requirements of other federal agencies should be considered valid by the EPA. EPA should not discount or ignore scientific studies that adhere to human subject privacy requirements established by National Institutes of Health (NIH), the Food and Drug Administration (FDA), and the Center for Disease Control and Prevention (CDC).

This NPRM does little to address the need for appropriate validation and analysis of scientific findings, supporting our shared interest in research that is both rigorous and reproducible. We are deeply troubled by the lack of sufficient information on how EPA's NPRM proposal would be operationalized and whether the NPRM proposal would even advance progress towards EPA's stated goal of using research "...in a manner sufficient for independent validation."

In summary, the ASIP believes that this Notice should be rescinded until such time as EPA provides more information on a variety of concerns, including the standards that will be used to evaluate past, current, and future research; and how the legitimate, ethical reasons for participant confidentiality would be balanced against interest in regulatory transparency.

Thank you for the opportunity to submit these comments. If the ASIP may be of further assistance, please contact Dr. William B. Coleman at wbcoleman@asip.org.

Sincerely,

William B. Coleman, PhD
Executive Officer

Cc: Thomas Sinks, Office of the Science Advisor