



February 21, 2024

Submitted Electronically to: <https://www.regulations.gov/>

RE: Response to EPA Scientific Integrity Policy Draft for Public Comment (EPA-HQ-ORD-2023-0240; FRL-10973-01-ORD)

To Whom It May Concern:

We write to offer comments in response to the Environmental Protection Agency's (EPA) publication of its draft [Scientific Policy](#) ("Policy") in the January 24, 2024, issue of the Federal Register. [89 FR 4606]. COGR is an association of over 200 public and private U.S. research universities and affiliated academic medical centers and research institutes. We focus on the impact of federal regulations, policies, and practices on the performance of research conducted at our member institutions, and we advocate for sound, efficient, and effective regulation that safeguards research and minimizes administrative and cost burdens.

COGR and its member institutions recognize the importance of ensuring that research is conducted in a transparent and objective manner in accordance with the highest standards of scientific integrity. We fully support EPA's issuance of the Policy and its stated purpose of enhancing and promoting a "continuing culture of scientific integrity." However, as detailed below, we are concerned that the Policy's language is too vague as to when and how it applies to the activities of recipients of EPA research awards ("Grantees"). This imprecision in drafting will make it difficult for Grantees to interpret and comply with the Policy. Accordingly, ***we urge EPA to modify the Policy to clearly describe how its various provisions apply to Grantees' research activities.***

Specifically, the Policy's section on "Applicability and Scope" states:

Covered entities who must adhere to the provisions of the policy include: all EPA employees, contractors, grantees, special government employees and advisory committee members. The policy applies when covered entities propose, conduct, or review science, communicate about science or scientific activities, or apply science to decision making; and to all levels of employees who manage or supervise scientific activities or use scientific information." [Footnotes omitted.]

The Policy then broadly defines "Covered Entities" as:

All EPA employees, political appointees, contractors, grantees, special government employees, and Federal advisory committee members. The policy applies when they propose, conduct, or review science, communicate about science and scientific activities, and apply science to decision making; and to all levels of employees who manage or supervise scientific activities and use scientific information. All cooperators, trainees,

interns, fellows, partners, co-regulators (e.g., other federal agencies, states, tribes, local municipalities), permittees, lessees, and volunteers who engage or assist in scientific activities are expected to uphold the principles of scientific integrity established by this policy and may be required to do so as part of their respective agreements with EPA. [Footnotes omitted.]

Given its broad scope, the Policy should clearly identify when and how it applies to Grantees' research activities. First, we recommend the Policy specifically state that it applies only to Grantees' research activities that are financially supported by EPA, as other funding agencies will expect their policies to apply to the research they fund. Second, we recommend the Policy make clear which of its provisions apply to Grantees (as opposed to other individuals/entities that fall under the definition of Covered Entities such as EPA employees and political appointees) and how they apply.

For example, the Policy states that "all appointed and career employees and *other covered entities* will receive scientific integrity training within 6 months of when their work at or with EPA commences" (*emphasis added*) and that this training will be tracked.¹ Does EPA contemplate that this training requirement will apply to all individuals and entities encompassed by the definition of Covered Entities? If so, will EPA be providing this training to Grantees and tracking their completion, or are Grantees expected to provide such training? In another example, the Policy states that it is EPA's policy to ensure the "independent validation of scientific and laboratory methods and models and that all novel methods or models are appropriately peer reviewed prior to use."² Is this provision meant to apply to Grantees that are conducting the research by which such models are first developed? If so, how should it apply? Will EPA provide the specified independent validation and/or peer review?

Conclusion

We appreciate the opportunity to offer comments on the RFI and hope that EPA will give serious consideration to the recommendations that we have offered. By clearly delineating when and how the Policy will apply to Grantee's research activities, EPA will help to ensure that Grantees appropriately interpret and implement the Policy. In turn, this will facilitate Grantees' ability to work with EPA toward the common goal of promoting scientific integrity.

Should you have any questions regarding this letter, please feel free to contact me or Kris West, COGR's Director for Research Ethics & Compliance at kwest@cogr.edu.

Sincerely,



Matt Owens
President

¹ [Policy](#) at p. 9-10.

² [Policy](#) at p. 11.