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Groups Seek Substantive Revisions to HHS Misconduct Regs, Investigations

By Theresa Defino

Two organizations representing research institutions and integrity officials have called for a virtual rewrite of the regulations that govern misconduct in Public Health Service-funded studies.

The Association of Research Integrity Officers (ARIO) and the Council on Governmental Relations (COGR) argued in a joint letter in response to a request for information (RFI) that the current regulations are 17 years old, which has given institutions “ample opportunity to see how [they] work in practice.”^[1]

Among the recommendations in their 12-page letter is to narrow “the scope of inquiries/investigations and the circumstances under which an inquiry or investigation may be closed.” The HHS Office of Research Integrity (ORI), which enforces research misconduct regulations, has “interpreted [relevant] provisions to greatly expand the scope of investigations beyond what the allegations and evidence suggest,” the organizations wrote.

This “overly broad scope may require universities to spend countless hours attempting to locate and assess information about rarely cited publications, unfunded proposals, unpublished research activities, and laboratory research records many years after their creation. This problem is compounded, and raises key process fairness concerns, when the respondent and/or key witnesses have left the institution and cannot be located or remain non-responsive to requests for information,” the groups said. “Requiring institutions to allocate scarce institutional resources to these frequently fruitless tasks hampers institutional efforts to address new or higher-impact concerns, as well as to conduct preventative and educational activities.”

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