

# Report on Research Compliance Volume 21, Number 2. January 25, 2024

## Three Agencies Expect to Issue New Regs, Revise Security, Privacy Rules

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Two HHS offices with oversight of federally funded research plan to issue three proposed and/or final rules this year affecting research misconduct and human subject protections. And medical schools and other institutions that provide health care as well as conduct research may see changes this year in the HIPAA Privacy and Security rules, enforced by the Office for Civil Rights (OCR). Then again, perhaps they won't.

The process of creating laws is often described as sausage-making—hidden, messy, something you maybe don't really want to see until it's done. There's a corollary to issuing regulations. The federal process of rulemaking is most visible in the *Federal Register* upon publication of requests for information, proposed, interim final and then final rules.

But before that happens, the drafting and finalization process plays out among agency staff with periodic mentions in the public but lesser-known Unified Agenda of Regulatory and Deregulatory Actions. Posted twice yearly—in spring and fall—the most recent version was published Dec. 6.

Because the regulated community can have the most impact during the drafting process, it's useful to keep abreast of what the rulemaking agencies are up to. When reviewing the Unified Agenda, however, it's important to note that the dates agencies list for issuing a regulation are estimates and are often missed, with subsequent updates containing later dates for publication—sometimes much later. In other instances, the agenda is outdated before it is even posted, and rules it reports as in process have already been issued.

With that as background, the following is regulatory news of note to research compliance officials organized by the agency involved.

### **No Date for ORI's Final Misconduct Rule**

As most know, the Office of Research Integrity (ORI), which investigates and makes findings of research misconduct—defined as fabrication, falsification and plagiarism—issued a proposed rule on Oct. 6.<sup>[1]</sup> As published, ORI provided a 60-day comment period and denied requests to extend the deadline.<sup>[2]</sup> However, ORI reversed itself and said it would accept comments until Jan. 4.<sup>[3]</sup>

The Unified Agenda, unusually, provides no updated information about when a final rule may be posted. It lists only the proposed rule publication and comment deadline dates.

As far as the substance of the proposed rule, that is known because it has been published. The agenda entry mostly describes how ORI operates, stating only that with a new rule, "ORI aims to clarify responsibilities, expectations, and processes; redirect respondent appeals of ORI findings or sanctions; and strengthen ORI compliance actions through updating the regulation."<sup>[4]</sup>

By mid-January, the comments of some 200 individuals and organizations had been posted online. RRC will

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review the comments in a future issue.

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