

## Report on Research Compliance Volume 19, Number 9. August 25, 2022

### OSTP Nominee Advances, But NIH, ORI–And Now OCR–Are Still Without Directors

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Among the concerns that investigators and institutional review boards must face, along with ensuring appropriate consent forms and compliance with other provisions in the Common Rule, is the privacy of research participants.

Additionally, HIPAA Privacy, Security and Breach Notification Rules apply to academic medical centers and other health care components of institutional systems that may not conduct research. Along with NIH, the Office of Research Integrity (ORI) and the Office for Civil Rights (OCR)—which enforces HIPAA regulations—are among the key agencies that can bring enforcement actions against them.

But as research compliance officials know, NIH has not had a permanent director since January; they're probably also aware that ORI—which investigates cases of research misconduct among the billions in NIH-funded research—has been in the same boat numerous times over the past decade: It's still being run by an acting or interim director.

Now OCR has been added to the list. In what appears to be the shortest tenure in OCR's history, Director Lisa Pino "departed" the agency sometime in August. But in more promising news, the Office of Science and Technology Policy (OSTP), which has been without a director since February, may soon have one, as might the National Cancer Institute (NCI).

Nothing seemed amiss at OCR until a two-sentence item appeared in *Politico*'s afternoon newsletter on July 12. "Melanie Fontes Rainer will be acting director of HHS' Office for Civil Rights, taking over from Lisa Pino, who is leaving the agency. Rainer previously was counselor to Secretary Xavier Becerra for health care," *Politico* reported.<sup>[1]</sup> Oddly, Pino is still listed on the OCR website as its director.

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