

Report on Research Compliance Volume 18, Number 12. November 25, 2021

Silent For 18 Months, OHRP Will Close Some Investigations in 2022, Plans to Issue Guidance

By Theresa Defino

It's been more than a year since the HHS Office for Human Research Protections (OHRP) signaled whether its compliance reviews or investigations have found institutions violating the Common Rule that safeguards study participants—or not violating the rule, as the case may be.

OHRP's determination letters are the only public evidence that OHRP is holding institutions accountable for people enrolled in research for which NIH and other Public Health Service agencies spend billions funding each year. Investigators and organizations also use the letters—when available—to learn about the mistakes of others and about best practices recommended to correct serious issues. These can include injury to a participant, lack of consent, inappropriate approval by an institutional review board (IRB) or violations of a protocol, among others.

As of late November, OHRP had posted zero determination letters this year. In response to a query from RRC, Lisa Buchanan, OHRP's director of the Division of Compliance Oversight, acknowledged the lack of letters and said none are expected before the end of 2021. A year with no letters—actually 18 months and counting—is a first for OHRP.

Buchanan maintained the lack of letters doesn't signal a cessation or decline in OHRP's oversight or enforcement activities. OHRP, she said, has 14 active investigative cases and that some will be closed "in the early part of next year." But the watchdog organization Public Citizen sees it differently, saying OHRP long ago abdicated its oversight responsibilities.

From 2007 to 2010, the office averaged 35 letters a year, down from a peak of 146 in 2002 and another high of 86 in 2006. RRC first began reporting on the marked drop in letters in 2011. In both 2017 and 2018, OHRP posted one letter. It issued two in 2019 and four last year.

This document is only available to subscribers. Please log in or purchase access.

[Purchase Login](#)