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Amid Criticism, OHRP Director Calls Determination Letters 'Case Shaming'

By Theresa Defino

In the coming months, the HHS Office for Human Research Protections (OHRP) plans to begin posting data about its oversight and compliance enforcement efforts, in response to a 2017 report by the agency's Office of Inspector General (OIG). The recommendation was made in light of OHRP's dwindling determination letters.

A watchdog organization also has accused OHRP of "abusing" its discretion about whether to open cases when violations of human subjects regulations are alleged.

But the agency seems wedded to its "informal" approach to enforcement, a move unlikely to increase the number of investigations or letters that result from them.

In fact, at a recent meeting, OHRP Director Jerry Menikoff said that revealing details about formal investigations can result in inappropriate "shaming" of institutions "that just happen ... to not comply with the regulations." He suggested that a focus on the letters stems from a desire to make his office look bad.

The letters describe the outcome of OHRP's investigations into allegations of noncompliance with 45 CFR part 46 , also known as the Common Rule. The correspondence, posted on OHRP's webpage, is also produced when OHRP completes not-for-cause evaluations of institutions conducting human subjects research.

Menikoff made his comments during the July meeting of the Secretary's Advisory Committee on Human Research Protections (SACHRP). Members were asked by HHS comment on last year's report, "OHRP Generally Conducted Its Compliance Activities Independently, But Changes Would Strengthen Its Independence."

As part of the public comment period of the SACHRP meeting, Michael Carome, formerly with OHRP, offered an impassioned defense of the letters and described what happens when investigations are opened. Director of the Health Research Group at Public Citizen, Carome also took issue with Menikoff's statements. He has regularly presented OHRP with allegations of noncompliance, including a recent complaint that led to significant changes in an NIH-funded cardiac study; his complaints are not always responded to by OHRP.

Closely scrutinized by regulated institutions, the letters provide the only public evidence of actions OHRP takes against institutions that are not in compliance with the federal human subject regulations. They are also instructive in describing OHRP's interpretation of the regulations in practice, as well as its current thinking on issues that may be common to many organizations. Supporters of the letters also say they hold institutions publicly accountable.