

## Report on Research Compliance Volume 15, Number 9. September 30, 2018

### Draft Guidance on New Common Rule Attracts Strong Responses From a Few

---

By Theresa Defino

“We desperately need new forest management practices.”

So begins a comment posted on regulations.gov in response to proposed guidance on scholarly activities deemed not to be research under the revised Common Rule, one of three recently released by the Office for Human Research Protections (OHRP). Of the 16 comments on the three, 11 are related to forest management practices, apparently assigned to the wrong document folder.

In addition to the scholarly activities draft guidance, OHRP addressed “When Continuing Review Is Not Required During the 6-Month Delay Period of July 19, 2018 through January 20, 2019: 2018 Requirements” and “Elimination of Institutional Review Board (IRB) Review of Research Applications and Proposals: 2018 Requirements.” These are the three provisions in the rule that organizations are permitted to implement before the January general compliance date (*RRC 8/18, p. 1*).

The process of revising the Common Rule governing human research has taken seven years, with delays due in part to the required analysis of the thousands of comments OHRP received when it issued various iterations of the regulation. When the final rule was published in 2017 in PDF form, 459 of 543 pages were devoted to responses to comments (*RRC 2/17, p. 1*).

#### **Journalist: Draft Guidance ‘Confusing’**

It may be welcome news to the agency that the three draft guidance documents OHRP issued in July have attracted so few comments, which should speed review and issuance of final documents.

The scholarly activities guidance drew three comments—one requested that it be withdrawn in its entirety. Two commenters on this draft guidance focused their attention on just the scholarly or just the journalistic provisions.

In his comments, Charles Seife, a journalist and professor of journalism at New York University, rejected the draft guidance as “confusing” and said it would “likely lead to the government imposing unconstitutional prior restraints upon journalists within academia.” If adopted as drafted, the guidance would “do more harm than good,” said Seife.

He noted that, although journalism “is specifically singled out as one of the categories that would often be exempt from these regulations,” the draft guidance characterizes as exempt “scholarly and journalistic activities...conducted in various fields that focus directly on the specific individuals about whom information is collected and used, without extending that information to draw generalizations about other individuals or groups.”

Much of journalism could be seen as “extending” and making conclusions that are not confined to an individual

---

subject of reporting, said Seife.

For example, “the journalistic profile, a form that most directly can focus on a single individual, typically uses that individual as a means for understanding something beyond that individual: to help the public understand the pressures on and motivations of group[s] of people he/she belongs to” and “to get a better sense of a broader happening that the person is part of,” Seife commented.

The draft guidance also poses a problem for oral history, as “academics” in this field “are also going to have difficulty calving off activities that fail to perform any generalization,” he wrote.

But Seife isn’t recommending revisions in the draft document. “It is better to leave the fine points of the distinction between regulated and unregulated activities unsaid,” and simply withdraw the proposed guidance, he said.

In their comments, Christine Pierre and David Vulcano, president and chair of the Regulatory Affairs Committee, respectively, for the Society for Clinical Research Sites (SCRS), said OHRP needs to better differentiate what the Common Rule means by a scholarly activity from the scholarly activity required of medical residents by the Accreditation Council for Graduate Medical Education.

They suggested that, without clarification, “many research projects that should go further down the decision tree (i.e. for an exempt determination or require IRB oversight) to be discounted because it is done for purposes of meeting the ‘Scholarly Activity’ requirement” of the council.

“We ask that it be more clearly stated that it is *the activities* of the research, not *the purpose*, that are evaluated to make this exclusion determination,” Pierre and Vulcano wrote.

This document is only available to subscribers. Please [log in](#) or [purchase access](#).

[Purchase Login](#)