

## Report on Research Compliance Volume 18, Number 1. January 02, 2021

### SACHRP Establishes 'Walls' for Public Health Surveillance Activities, Stresses Accountability

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More than two years ago, as institutions were in the throes of readying to comply with the revised Common Rule, the HHS Office for Human Research Protections (OHRP) issued draft guidance on public health surveillance activities not considered to be research.<sup>[1]</sup> Fast forward two years, and the world has changed drastically as the globe grapples with the COVID-19 pandemic, which has put greater focus on the topic of the proposed guidance like never before.

In fact, the first COVID-19 case in the United States was confirmed through the sequencing and analysis of samples originally collected as part of the Seattle Flu Study. The University of Washington's institutional review board (IRB) issued a waiver of consent for the use of residual samples for COVID-19 testing purposes.<sup>[2]</sup> A related report about the Seattle research indicated that an IRB "determined that results could be reported to public health authorities and to participants, who were notified under a public health surveillance exemption."<sup>[3]</sup>

Its guidance still in draft form, OHRP asked the Secretary's Advisory Committee on Human Research Protections (SACHRP)—which it had not consulted in the writing of the proposed document—to weigh in. "The context of the pandemic brought this issue up because people were actually struggling with this exception," and issues were "raised explicitly in the context of the challenges of IRB review in the pandemic," SACHRP Chair Stephen Rosenfeld told RRC.

SACHRP completed the task, answering eight questions posed by OHRP, commenting (briefly) on the proposed guidance and offering an algorithm for determining when a public health exclusion applies.<sup>[4]</sup> OHRP posted the recommendations in November.<sup>[5]</sup>

Specifically, the recommendations give SACHRP's insights into the practical application of public health authority and public health surveillance activities, 45 C.F.R. § 46.102(k) and 45 C.F.R. § 46.102(l)(2) .

As SACHRP explained, prior to 2018, the Common Rule enumerated exempt study activities still considered research. The revised rule "modified extensively" the exemptions as well as revising the definition of research to include four activities that "are deemed not to be research." The final revised Common Rule dropped the use of the word "exclusions."

Members noted that there is "conceptual uncertainty as to whether the four exclusions are not research or alternatively are research that does not require compliance with the 2018 Requirements," similar to the exemptions at 45 C.F.R. § 46.104 . Ultimately, committee members concluded that "that distinction does not have practical implications and does not need to be resolved in order to apply the exclusions" for public health surveillance.

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