Report on Research Compliance Volume 15, Number 11. November 30, 2018

SACHRP Offers Help With Common Rule's Key Information Requirement

By Theresa Defino

Changes to informed consent documents, including the addition of "key information," are among the requirements in the new revised Common Rule that will be most visible to research subjects, and thus a likely priority for institutions conducting human subjects research to implement.

The revised rule goes into effect Jan. 21 for most requirements, although studies that were voluntarily transitioned after the July allowable date (triggered when certain "burden-reducing" provisions are adopted) may already be complying with the updated regulation (*RRC 5/18, p. 1*).

Under the revised rule, consent forms must now address biospecimens, commercial use of samples and the sharing of research results, changes that are relatively straightforward (see box, p. 4).

With the expectation that it will be issuing guidance, the Office for Human Research Protections (OHRP) asked its advisory panel to weigh in on the key information requirement. At their Oct. 16-17 meeting, members of the Secretary's Advisory Committee on Human Research Protections (SACHRP) completed a series of recommendations related to key information, and offered a list of questions to guide institutions and investigators as they draft this new section. Perhaps equally or more useful is a list of questions SACHRP developed that institutional review boards and investigators can ponder when trying to narrow down what to include in the key information section.

SACHRP also offered recommendations for how to handle various provisions when transitioning studies to the new requirements, although it strongly recommends not applying the new rule before January unless legally required to do so (see story, p. 1). In other action, the committee approved categories and types of studies for consideration under new expedited review provisions; these will be discussed in a subsequent issue of *RRC*.