Report on Research Compliance Volume 15, Number 5. May 31, 2018 SACHRP Approves FAQs for 'Broad Consent,' Studies Using Biospecimens

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At its first meeting of 2018, the Secretary's Advisory Committee on Human Research Protections (SACHRP) approved a series of FAQs designed to help institutional review boards (IRBs), investigators and research compliance officials implement new provisions in the revised Common Rule.

Specifically, SACHRP adopted five new FAQs related to recommendations on the new concept of broad consent, and 25 that add to and update existing FAQs on "informed consent and research use of biospecimens and associated data." It took the actions at its March meeting.

Broad consent is a new concept that was added to the Common Rule. The Office for Human Research Protections (OHRP) asked SACHRP to develop guidance on the "interpretation and implementation of the broad consent proviso." SACHRP's recommendations should prove useful, as OHRP must create guidance documents now that the general compliance date of the revised Common Rule is in January (see story, p. 1).

The new FAQs are in addition to a guidance document on broad consent that SACHRP approved in July, which addressed the "two new exemption categories under which research is excepted from compliance with the entire Common Rule if it satisfies certain abbreviated conditions, including obtaining the subject's broad consent."