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FDA Seeks Comment on Two NPRMs

By Theresa Defino

With one still awaiting finalization since 2018, the Food and Drug Administration (FDA) has published two additional proposed rules implementing portions of the 2016 Cures Act as well as making other somewhat technical corrections to its regulations.

Nov. 28 is the comment deadline on both notices of proposed rulemaking (NPRM), which were published Sept. 28. Some of the changes would harmonize certain FDA regulations with some parts of the revised Common Rule, but the agency is not adopting the concept of broad consent, for example.

The NPRMs are "Protection of Human Subjects and Institutional Review Boards" (IRBs)[1] and "Institutional Review Boards; Cooperative Research."[2]

If finalized as proposed, the human subjects and IRBs NPRM would revise 21 C.F.R. § 50, specifically "the content, organization, and presentation of information included in the informed consent form and process to facilitate a prospective subject's decision about whether to participate in the research," Ann Meeker-O'Connell, director of the FDA Office of Clinical Policy explained during a recent meeting of an HHS advisory committee.[3]

The terms that will have new or revised definitions include legally authorized representative, written or in writing, private information, identifiable private information and identifiable biospecimen.

New Biospecimen Consent Language Proposed

"One subtle difference from the Common Rule in our proposed definition of both identifiable private information and identifiable biospecimens is that…we propose to add sponsors in addition to investigators as parties who may reasonably or readily ascertain information or the identity of the subject," she said. "These terms—sponsor, investigators—are used throughout our regulations to describe different responsibilities of distinct parties involved in FDA regulated research."

She noted FDA's proposed rule requires consent forms to include "a description of how information or biospecimens may be used for research or distributed to another investigator for future research."

In contrast, Meeker-O'Connell said, the Common Rule requires a statement specifying that biospecimens either will be used for future research without obtaining additional consent or that they will not.

"This proposal is really intended to incorporate flexibility as to the description that an investigator would provide to each potential subject or their legally authorized representative to help ensure that they are informed regarding possible future uses of information or biospecimens that are collected from their participation in research," Meeker-O'Connell said.

"This flexibility is needed, as the ways in which information and biospecimens are used relevant to FDA regulated products really continue to evolve," she said. "We also believe that the inclusion of a description of how

information and biospecimens may be used for future research or distributed to another investigator for such research will help potential participants to identify the types of planned future research using their information or using their biospecimens that they might deem objectionable, recognizing that the specific details of potential future studies may be unknown."

FDA officials, she added, "think the research community would be able to develop informed consent forms and processes that comply with both sets of regulations when applicable."