FDA Amends Informed Consent Requirements for Drug and Device Clinical Trials

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All stakeholders involved in U.S. Food and Drug Administration-regulated clinical trials should begin now to plan for transitioning to use of informed consents that meet the specific requirements of the new rule.

On January 4, 2011, the U.S. Food and Drug Administration (FDA) published its final rule amending current regulations governing the informed consent process for clinical research studies of products regulated by the FDA, at 21 C.F.R. § 50.25(c).

The final rule requires that all informed consent documents for "applicable" drug (including biological product) and device clinical trials initiated on or after March 7, 2012, include a statement to inform individual subjects in the trials that a description of the clinical trial will be made available on the National Institutes of Health/National Library of Medicine (NIH/NLM) website at clinicaltrials.gov. The statement must also indicate clinicaltrials.gov will not include individually identifiable information.

According to the final rule's preamble, the statement may be included anywhere in the informed consent document; however, the document must use the exact language set forth in the rule. The new informed consent requirements apply to "applicable clinical trials" as they are defined in section 282(j) of the Food and Drug Administration Amendments Act of 2007. Additional information regarding the NIH's interpretation of "applicable" drug and device clinical trials is available on the NIH/NLM website.

The preamble to the final rule includes important compliance information, such as how to coordinate compliance where multiple investigation sites are involved. It also clarifies how the informed consent requirements work with regulations governing FDA-regulated products and U.S. Department of Health and Human Services (HHS) regulations governing research conducted or supported by HHS. For example, the preamble provides:

- The informed consent statement is *not* required if the trial is not an "applicable clinical trial"
- The required statement must be included in informed consent documents for clinical trials conducted outside the United States if the trial is still subject to FDA's jurisdiction
- The language regarding availability on clinicaltrials.gov must be included in an informed consent document regardless of whether an Institutional Review Board determines that the information

concerning submission of aggregate results to clinicaltrials.gov does not need to be included in a HIPAA authorization form

- Re-consent is not required for clinical investigations that were initiated before the March 7, 2012, compliance date

The preamble also provides that the FDA has several options available to enforce the new informed consent requirements, including the authority to seek administrative, civil and criminal penalties.

The final rule becomes effective March 7, 2011; however, the FDA will not enforce the requirements until March 7, 2012. Nonetheless, given the fluid nature of clinical trials, it will be important for sponsors, institutions, investigators, contract research organizations and institutional review boards to begin now to develop a thorough and well-coordinated plan for properly transitioning to the use of new informed consent documents, training employees and monitoring the status of clinical investigations (i.e., those in development and those that have already started prior to the compliance date) to ensure proper compliance, particularly where multiple trial sites may be involved.