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Client Alert

FDA & Life Sciences Practice

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New Required Informed Consent Element – Disclosure that Clinical Information will be Entered into ClinicalTrials.gov

FDA Final Rule Amends Current Regulations Governing Informed Consent of Potential Clinical Trial Participants

The Food and Drug Administration (FDA) issued a final rule on January 4, 2011 that amends 21 C.F.R. § 50.25 and the requirements for informed consent documentation and process in FDA-regulated clinical trials of drugs, biological products, and medical devices.[1]

The final rule responds to Section 801 of the FDA Amendments Act of 2007 (FDAAA),[2] which requires registration and results posting in the federal data bank, ClinicalTrials.gov, for "applicable clinical trials" of FDA-regulated drugs and medical devices.[3] FDAAA mandated that FDA's drug regulations be updated "to require inclusion in the informed consent documents and process a statement that clinical trial information for such clinical investigations has been or will be submitted for inclusion in the registry data bank." The final rule requires the following statement to be included in the informed consent documents and process of "applicable clinical trials" for both drugs (including biological products) *and* medical devices:

"A description of this clinical trial will be available on http://www.Clinical Trials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."

The new rule has important implications for sponsors of FDA-regulated clinical trials conducted in the United States and other countries.

- **Compliance date.** The rule is effective March 7, 2011. The compliance date is March 7, 2012 (*i.e.*, one year after the effective date) for clinical trials that are initiated on or after the compliance date. Modification of consent processes and "re-consent" will not be required for "applicable clinical trials" initiated prior to March 12, 2012.

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- **The specific statement may not be modified.** The specific statement must be included in informed consent documents of "applicable clinical trials" exactly as stated in the final rule. It cannot be modified by investigators, sponsors, or IRBs. However, in the preamble, FDA clarifies that nothing in the rule prohibits an investigator, sponsor, or IRB from "including further explanation on the nature and confidentiality of information submitted to ClinicalTrials.gov," or from describing other clinical trial publication or registry approaches (*e.g.*, voluntary publication; voluntary registration; ex-U.S. registration requirements).

- **Revision of informed consent templates and processes.** The new informed consent element is required only for "applicable clinical trials," not all clinical trials. Sponsors will need to ensure that there is an internal process to identify those clinical studies that are subject to the new informed consent requirement, and to distinguish covered documents and processes from those for clinical studies that are not "applicable clinical trials." Sponsors should ensure that persons knowledgeable about pertinent regulatory requirements make the judgment whether studies are "applicable clinical trials," as this definition underlies other registration and results posting requirements (and could raise compliance issues if inconsistently or inappropriately applied).

- **Training of investigators.** Sponsors will also need to ensure that investigators and site personnel are fully trained to engage in the revised informed consent process with potential human subjects. The company's investigators should be trained and capable of accurately describing the ClinicalTrials.gov data bank in discussions with potential human subjects.

- **Transparency.** In the preamble, FDA discusses its expectation that the new rule will increase clinical trial participant awareness of the existence of clinical trials, progress of the trials in which they are enrolled, and certain clinical trial results. FDA also anticipates that the rule will provide "greater accountability of clinical trial investigators for outcomes and adverse events." Sponsors may wish to ensure that the company's clinical trial personnel and investigators are prepared for increased scrutiny by clinical trial participants of information on ClinicalTrials.gov regarding the trials in which they are enrolled.

Please contact us if you have questions about FDA's new final rule on "Informed Consent Elements" or the requirements of FDAAA regarding the registration and reporting of results of "applicable clinical trials" in the federal data bank, ClinicalTrials.gov.

[1] 76 Fed. Reg. 256 (Jan. 4, 2010).
[2] See § 801(b)(3)(A) of the FDA Amendments Act of 2007 (Pub. L. 110-85, Sept. 27, 2007).
[3] The term "applicable clinical trial" is defined at 42 U.S.C. § 282(j)(1)(A).