

FDA Publishes Revised Informed Consent Regulations

The Food and Drug Administration ("FDA") has adopted final amended informed consent regulations. The FDA Amendments Act ("FDAAA") § 801(b)(3)(A) requires that the FDA amend the informed consent regulations set forth at 21 C.F.R. § 50.25 to include a statement to inform potential clinical trial participants that data from the trial has been or will be entered into a databank accessible to the public via www.clinicaltrials.gov. The rule will become effective on March 7, 2011, and the FDA is providing a grace-period of 1 year, stating that it intends to enforce the rule only for informed consent documents that are initiated on or after March 7, 2012. Therefore, existing informed consents do not need to be modified to comply with this rule.

The statement that is required by amended 21 C.F.R. § 50.25 reads: "A description of this clinical trial will be available on www.clinicaltrials.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 anytime." Sponsors and institutions should revise their clinical trial informed consent templates to include the required language.

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