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Presenting a live 90-minute webinar with interactive Q&A

Clinical Trials Disclosure and Reporting Compliance

Navigating Overlapping and Evolving Federal and State Transparency Requirements

THURSDAY, MARCH 31, 2011

1pm Eastern | 12pm Central | 11am Mountain | 10am Pacific

Today's faculty features:

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The audio portion of the conference may be accessed via the telephone or by using your computer's speakers.

Please refer to the instructions emailed to registrants for additional information. If you have any questions, please contact **Customer Service at 1-800-926-7926 ext. 10**.

McGUIREWOODS

Legal Updates

3/2/2011

New Requirement for Informed Consent in Clinical Trials

Under a rule released recently pursuant to § 8.01(b)(3)A of the 2007 FDA Amendments Act (FDAAA), Pub. L. 110-85, 42 U.S.C. 282(i), FDA now requires that informed consent documents in clinical trials of drugs, devices and biologics include a specific statement informing subjects that de-identified trial information will be posted at ClinicalTrials.gov, the clinical trial registry data bank maintained by the NIH and the National Library of Medicine.

The new language is obligatory: "A description of this clinical trial will be available on ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time." 21 C.F.R. § 50.25(c).

Investigators had long been required to inform participants of "a description of any benefits to the subject or to others which may reasonably be expected from the research." 21 C.F.R. § 50.25(a)(3). Reference to the data bank website is intended to help participants recognize that, even though clinical research is not itself designed to provide therapeutic benefits to individual subjects, participation in the trial contributes to the advancement of medical knowledge. Like other informed consent elements, this new one is subject to all the other regulations governing documentation of informed consent, 21 C.F.R. § 50.27, and IRB waivers, 21 C.F.R. 56.109.

The new requirement applies only to "applicable clinical trials" as defined in the FDAAA, 42 U.S.C. 282(j)(1)(A), § 402(j)(1)(A) of the PHS Act, and any relevant regulations. Hence, the new rule applies to some trials but not others. Under FDAAA's statutory definition, a Phase 1 or device feasibility study, for example, or one not subject to FDA regulation, as is often the case in non-U.S. trials, would not be considered an applicable clinical trial. On the other hand, the requirement does extend to clinical trials conducted abroad pursuant to an IND or otherwise subject to FDA's jurisdiction.

In clinical investigations initiated before the compliance date, reconsent based solely on the new requirement will not be required. Nor will compliance with the new § 50.25(c) be required if the informed consent documents of the ongoing clinical investigation have to be amended for any other purpose, and reconsent of the already enrolled or actively participating clinical trial participants is required for that other purpose.

The policy underlying the new requirement is well-established – FDA wants subjects to be acquainted with the benefits and risks anticipated from participation in trials, and with the public's access to de-identified data respecting such trials. Subjects who take the time to read the new language may not be unduly concerned. If, however, some subjects – confronted with an informed consent document even longer than what was used in the past – mistakenly fear a loss of privacy protection sufficient to chill participation, the cost of the new approach could outweigh its benefits. As is often the case, time will tell whether this potential problem is realized.

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MORE INFORMATION

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