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HEALTHCARE LAW PRACTICE GROUP NEWS REPORT

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INFORMED CONSENT COMPLIANCE IN CLINICAL TRIALS ARE YOU READY?

By: Jeffery M. Wyble, Esq.

On March 7, 2012, the Food and Drug Administration ("FDA") will begin enforcement of the recently amended 21 C.F.R. § 50.25 informed consent documentation and process requirement for applicable clinical trials. Specifically, 21 C.F.R. §50.25(c) requires a statement in an applicable clinical trial's informed consent documents informing trial participants that a description of the clinical trial will be available on the clinical trial registry, www.ClinicalTrials.gov. The purpose of 21 C.F.R. §50.25(c) is to reduce the risk of inaccurate and confusing statements to trial participants regarding the registration of clinical trial information and to promote clinical transparency of clinical research.

Background. The Food and Drug Administration Amendments Act of 2007 ("FDAAA") requires registration of all Phase II-IV FDA-regulated clinical trials involving drugs, biological products and medical devices ("applicable clinical trials"). The U.S. National Library of Medicine at the National Institute of Health maintains the registration database, which is accessible at www.ClinicalTrials.gov. The FDAAA also required the FDA to revise its informed consent regulations to require informed consent documents and processes for applicable clinical trials to include a statement regarding such clinical trials' registrations at www.ClinicalTrials.gov.

On January 4, 2011, the FDA published its final rule amending its informed consent regulations under 21 C.F.R. Part 50 pursuant to the FDAAA.[1] This final rule, codified at 21 C.F.R. § 50.25(c), became effective on March 7, 2011. Specifically, 21 C.F.R. § 50.25(c) states that all informed consent documents for applicable clinical trials must contain the following statement: "A description of this clinical trial will be available on http://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 any time."

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Commencement Date. All informed consent documents for applicable clinical trials initiated on or after March 7, 2012 ("commencement date") must contain the 21 C.F.R. § 50.25(c) statement. The Federal Register notice states "initiated" means "if the sponsor/investigator has had any informed consent documents for that clinical investigation cleared or approved by an IRB, a regulatory body or other human subjects review entity."[2] Therefore, any applicable clinical trial initiated before the commencement date is not required to comply with 21 C.F.R. § 50.25(c).

Amended Informed Consent Documents. Amended informed consent documents are not required to contain the 21 C.F.R. § 50.25(c) statement if the applicable clinical trial was initiated before the commencement date.

Multisite Clinical Trials. If one or more sites in an applicable multisite clinical trial was initiated before March 7, 2012, then the informed consent documents for the remaining clinical trial sites are not required to comply with 21 C.F.R. § 50.25(c), regardless if future sites begin their clinical trials after the commencement date.

Reconsent. Trial participants are not required to reconsent based solely on the 21 C.F.R. § 50.25(c) requirement for applicable clinical trials initiated before the commencement date.

Clinical Trial Location. All applicable clinical trials are subject to 21 C.F.R. § 50.25(c), including trials conducted outside of the United States.

Modification Prohibited. The party responsible for preparing informed consent documents is prohibited from modifying the 21 C.F.R. §50.25(c) statement. However, the regulation does not prevent the responsible party from including additional information regarding the clinical trial's registration at www.ClinicalTrials.gov.

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Enforcement. The FDA has several options available for enforcing 21 C.F.R. §50.25 even though there is no express penalty set forth in the body of the regulation. The FDA's authority to issue regulations to protect human test subjects also includes the authority to impose penalties for violating such regulations. Specifically, "section 301(e) of the Federal Food, Drug, and Cosmetic Act ("FD Act") (21 U.S.C. 331(e)) makes the 'failure to establish or maintain any record, or make any report, required under section * * * 505(i) * * *' and the "failure or refusal to comply with any requirement prescribed under section * * * 520(g)" prohibited acts. The FD Act and implementing regulations allow FDA to seek administrative, civil, and criminal penalties for violations of section 301 of the FD Act. 21 U.S.C. § 303(a); §§ 312.44(b)(1)(ix), 312.70(a), 812.30(b)(4), 812.119(a), 56. 121(b)."[3]

Sponsors, investigators and IRBs should take time now before March 7, 2012 to review their procedures for determining "applicable clinical trials" and revise their informed consent documents to comply with 21 C.F.R. § 50.25.

For questions regarding the FDAAA registration requirements of "applicable clinical trials" in the clinical trial registry, www.ClinicalTrials.gov, or compliance with 21 C.F.R. § 50.25, please do not hesitate to contact our Health Care Law attorneys at Schenck, Price, Smith & King, LLP at **973-539-1000**.

[1] Informed Consent Elements, 76 Fed. Reg. 256 (codified at 21 C.F.R. § 50.25)
[2] Id. at 259.
[3] Id. at 265.