



FDA Issues Two Guidance Documents—One Final, One Draft

The Federal Register contains two new guidance documents from the Food and Drug Administration (FDA). The first is a final guidance documents, titled “Computerized Systems Used in Clinical Investigations” (72 Fed. Reg. 26638, May 10, 2007). According to the FDA, “this guidance is intended to assist in ensuring confidence in the reliability, quality, and integrity of electronic source data and source documentation, i.e., electronic records. This guidance supersedes the guidance entitled ‘Computerized Systems Used in Clinical Trials,’ dated April 1999; finalizes the draft guidance of the same title dated September 2004; and supplements the guidance for industry entitled ‘Part 11, Electronic Records; Electronic Signatures—Scope and Application,’ dated August 2003, and FDA’s international harmonization efforts when applying guidance to source data generated at clinical study sites. “Link:

<http://a257.g.akamaitech.net/7/257/2422/01jan20071800/edocket.access.gpo.gov/2007/E7-9056.htm>

The second is a draft guidance document, titled “Protecting the Rights, Safety, and Welfare of Study Subjects—Supervisory Responsibilities of Investigators” (72 Fed. Reg. 26639, May 10, 2007). According to FDA, “This draft guidance is intended to assist investigators in meeting their responsibilities with respect to protecting human subjects and ensuring the integrity of data in the conduct of clinical investigations. The draft guidance also clarifies FDA’s expectations concerning the investigator’s responsibility for supervising a clinical study in which some study tasks are delegated to employees of the investigator or to outside parties.” Comments will be accepted until July 9, 2007. Link:

<http://a257.g.akamaitech.net/7/257/2422/01jan20071800/edocket.access.gpo.gov/2007/E7-9055.htm>