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Good Clinical Practice Q&A: Focus on Date Stamps

What are the rules regarding the use of a signature or date stamp in clinical studies, and is the use of such stamps consistent with GCP standards?

In a recent response to a question regarding the use of date stamps, the FDA stated that agency "regulations do not specifically address the signing or dating of documents by the clinical investigator, nor do the regulations prohibit the use of date stamps by clinical investigators." Sites therefore have flexibility in how they handle documents at their sites because FDA's regulations do not specify how this must be done. [We] would suggest that if your site is contemplating the use of date or signature stamps, from a practical standpoint, you might wish to consider developing standard operating procedures (SOPs) for their use. If a signature stamp were to be employed, the SOP should address any necessary controls over the stamp, for example, who is authorized to use the stamp, where the stamp is stored, and how access to the stamp is controlled, the type(s) of correspondence on which it may be used, and the circumstances for its use (e.g., cover letters providing routine or general information). If your site subsequently follows the SOPs you develop, then it would appear to be acceptable and in keeping with good clinical practice.

In practice, some clinical settings permit the use of a rubber stamp on medical records. When it is used, the impression should be initialed in script, and there must be supporting documentation matching the stamp signature with an original signature.

Rubber stamps should be used in clinical studies in a very limited manner — that is, on hospital medical records, if permitted by the hospital and if initialed and dated. As part of the site selection process, the sponsor should evaluate the site's methods for creating and maintaining medical records. If a rubber stamp is routinely used at the investigator's office/clinic or participating hospital, the rules regarding its use should be discussed with site staff prior to the study's initiation at that site.

A stamp should not be used for key documents, such as the Form FDA 1572 – Statement of Investigator, protocol signatures, or informed consents. According to FDA's May 2010 guidance titled, "Frequently Asked Questions – Statement of Investigator (Form FDA 1572)," a completed 1572 "must be signed and dated by the investigator (either by hand or using an acceptable electronic method)."

Source

"Good Clinical Practice: A Question & Answer Reference Guide", Barnett International. The Guide is available at http://www.barnettinternational.com in electronic and paper form.