Good Clinical Practice Q&A

Is the use of a signature stamp or digital/e-signature acceptable, or is it prohibited? In instances where a PI is unavailable, who else is authorized for consultation in their place (for randomization purposes, correspondence or IRB paperwork)? With increased use of e-consent, how do investigators sign?

FDA regulations do not specifically address 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 SOPs 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 that you develop, it would appear to be acceptable and in keeping with good clinical practice. From a regulatory standpoint, since staplers can be used by anyone who gains access to them, the use of staplers would not be acceptable where verification of who accomplished a task and/or when it was accomplished is information required by regulation. Documentation needs to be provided in a manner that can be verified as unique to the individual who is indicated as “signing” the document. The FDA published a guidance, “Use of Electronic Informed Consent in Clinical Investigations,” which establishes guidelines for investigators managing electronic informed consent. The guidance conveys openness in using electronic consent (eIC).

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