

Good Clinical Practice Q&A: Focus on Investigator Credentials

Do CVs expire in the same way a medical license does when collecting these documents to support investigators listed on the 1572?

This is probably one of the most misunderstood and over-documented issues in GCP. It has, over the years, become industry practice to have investigators and subinvestigators sign and date their CVs, to obtain a new, updated CV every two years, to have these documents expire, and to require updating them.

The FDA, in its May 2010 guidance entitled, "Frequently Asked Questions—Statement of Investigator (Form FDA 1572)," as well as numerous presentations over the years, has indicated that FDA regulations do not require a CV or other statement of qualifications to be signed and dated or to be updated during a clinical study. According to the guidance, the signed and dated signature of the investigator on Form 1572 is their attestation to the completeness and accuracy of the information (including their CV). In a recent presentation from FDA when asked a similar question, the FDA responded that, "the purpose of collecting the CV (and license) is to document that at the time the investigator was hired to conduct the trial that he or she is qualified by training, education and experience." If the investigator is considered qualified at the beginning of the trial, is it likely that he or she would become less qualified as time goes on? So what is the purpose of collecting an updated CV later? In contrast, a medical license does need to be renewed every two to three years in the U.S., due to state licensing laws, so collecting an updated medical license may be appropriate. However, note that, in many countries, a medical license does not expire, and once a physician is licensed he or she does not need to renew it on a regular basis, as is required in the U.S.

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.