

Good Clinical Practice Q&A: Focus on Form 1572

Is it important that a clinical investigator's name as provided in the 1572 exactly match the name on his/her medical license – for example, if the medical license states, "Dr. M.P. Jones," while the 1572 lists the investigator as Dr. Michael Paul Jones?

In an informal response to this question, the FDA states that, "the regulations themselves are not explicit here; but in general, the 1572 should list the investigator's legal name (first name, middle name or initial, last name, and any suffix). This should but may not be identical to the medical license (as in the example where the medical license permits use of initials throughout)... The 1572 is not a documentation of medical licensure per se (since medical practice is regulated by the state and not by the federal government)."

Is it true, as some claim, that the 1572 must be double-sided and not printed on two pages? Is this an FDA requirement or policy?

In an informal response to this question, the FDA stated that, "FDA regulations do not specify that the Form FDA 1572 must be double-sided, nor does FDA have a set policy on this. [It is] recommended, however, that if a two-page form is used, the pages should be stapled together so there is no doubt as to the form a particular investigator signed."

References

1. "Good Clinical Practice: A Question & Answer Reference Guide", Barnett International, 2007 p. 66
2. Ibid., p. 67

Source

"Good Clinical Practice: A Question & Answer Reference Guide 2007," is available for \$39.95 at <http://www.barnettinternational.com/>