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Good Clinical Practice Q&A: Focus on Form 1572

If a clinical site uses its own medical center laboratory to perform a blood draw, and packages and ships blood samples to a central laboratory that performs all of the analyses for the study, does the medical center lab need to be listed in the 1572's Section #4-Name and Address of Any Clinical Laboratory Facilities To Be Used in the Study?

In an informal response to this question, the FDA stated that, "it is our opinion that block #4 of the 1572 is intended to identify clinical laboratories or testing facilities that directly contribute to or support the clinical trial (e.g., diagnostic labs performing blood work, imaging centers, cardiology labs, etc.). If a laboratory or testing facility is performing procedures required by the study protocol for collection of significant endpoint safety or efficacy data, then it should be listed in block #4. In the scenario [described in the question], the central laboratory that analyzes the samples to meet study protocol requirements/procedures should be listed in block #4 of the 1572. The location of the medical center laboratory that collects the blood sample appears to already be identified in block #3-Name and Address of Any Medical School, Hospital or Other Research Facility Where the Clinical Investigation(s) Will be Conducted. The medical center laboratory need not be identified in block #4 unless and until it performs analysis of biological samples."[1]

Reference

1. "Good Clinical Practice: A Question & Answer Reference Guide", Barnett International, 2011, #3.52 p. 113

Source

"Good Clinical Practice: A Question & Answer Reference Guide 2011," is available for $45.95 at http://www.barnettinternational.com in electronic and paper forms.