



3-Minute GCP Quiz™ Monitoring February, 2009

	Question	Answer
1	A monitor is required to inspect case report forms for legibility, accuracy and completeness.	True
2	Monitoring visits require an inspection of medical records as part of the process for verifying protocol compliance.	True
3	A typical responsibility of the monitor is to train the local IRB personnel in GCP in conjunction with the first monitoring visit.	False
4	Pre-study visits should include an assessment of the investigator's financial status with the IRS to rule out any unanticipated problems with study finances.	False
5	GCP does not require monitors to evaluate original medical records that have been prepared on paper, provided the investigator provides access to electronically scanned copies of the records.	False
6	Monitors are required by GCP to inform investigators of observed deficiencies during the monitoring process and define the actions necessary by the investigator to correct the observed deficiencies.	True
7	Monitors are required to verify source documents and determine whether there is adequate support for data in the CRFs.	True
8	The role of the monitor does not typically include making a comparison of the sponsor's documents and the investigator's documents at the close of the study.	False
9	The monitor's evaluation of investigational supplies includes an assessment of the quantity of supplies available for future subjects, the quantity of supplies available for currently enrolled subjects, and the expiration dates of all supplies.	True
10	Monitors are responsible for ensuring that investigators and their designees have properly documented any corrections on CRFs.	True
11	According to GCP site monitoring visits should typically include a visit to the local IRB office to verify that the IRB is in compliance with GCP.	False
12	Re-labeling of any unused, marketed supplies for use in the investigator's medical practice is a typical responsibility of a monitor during a study close out visit.	False

Want More Information?

We hope you have enjoyed testing your GCP knowledge with this quiz. Please feel free to share this with your colleagues. The correct answers to this quiz will be posted on our website www.RANInstitute.Com during March, 2009.

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