



3-Minute GCP Quiz™
Inspection of Investigator's Records
May, 2008
Answers appear in red bold text

	Question	Choose the Correct Answer(s)
1	<p>To which of the following does GCP grant authority to conduct inspections of a clinical investigator's records?</p> <p>See the ICH GCP Guideline</p>	<p>A. The sponsor B. The IRB or IEC C. Regulatory authorities D. National medical associations. E. Local government officials</p>
2	<p>Select ALL of the following rights that are granted to a sponsor's monitor by the term "DIRECT ACCESS" as it is defined in GCP.</p> <p>See the ICH GCP Definition of Direct Access</p>	<p>A. Direct access allows the monitor to inspect other medical records within the institution where the records are located. B. Direct access allows the monitor to examine, analyze, verify, and reproduce any records or reports deemed important to evaluation of the trial. C. Direct access allows the monitor to access all of a study subject's personal health information. D. Direct access allows the monitor to publish reports of observations made during the inspection in public domains.</p>
3	<p>GCP requires investigators to take measures to prevent premature or accidental destruction of study records. Therefore, this implies that those investigators residing in areas that are subject to severe weather and related events should establish a plan to ensure the safeguarding of records should such an event occur.</p>	<p style="text-align: center;">True or False ?</p>
4	<p>Regulatory authorities are permitted under GCP to request relevant records for inspection from an IRB or IEC for a period of up to two years following the completion of the study.</p>	<p style="text-align: center;">True or False ? IRB records may be inspected for 3 years.</p>
5	<p>The regulatory authority inspection criteria for clinical investigators who conduct studies within a private medical practice differs from the inspection criteria for investigators who are affiliated with an institution, such as a university or hospital.</p>	<p style="text-align: center;">True or False ? The Inspection criteria do not vary based upon the practice location of the clinical investigator.</p>
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