

**GCP Quiz Questions and Answers
Investigator's Responsibilities
November, 24, 2008**

Are the following True or False?

1. Investigators are required to endorse changes made to CRFs by the sponsor representatives.

True: See ICH GCP Guideline 4.9.4

2. The term direct access means that investigators must agree to provide sponsors, the FDA and other authorized personnel with access to all records related to a subject's participation in a clinical trial.

True: See ICH GCP Guideline 1.21

3. An investigator may delegate any study responsibility to any member of his/her support staff.

False: See ICH GCP 4.1.5 and 21 CFR 312.53, and FDA Form 1572, Statement of Investigator, Section 9, Commitments

4. According to GCP, investigators initiate clinical studies and sponsors conduct clinical studies.

False: See ICH GCP 1.34, 1.53 and the FDA's regulation, 21 CFR 312.3

5. The contract between a sponsor and an investigator is a private document and therefore not considered to be an essential document according to ICH GCP.

False: See ICH GCP Guideline 8.2.4 and 8.2.6

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