



3-Minute GCP Quiz™

Financial Disclosure & Contracts

	ANSWERS	Answer
1	The purpose of disclosing financial information and interest in a particular clinical study is to support the FDA's evaluation of marketing applications for drugs, biologics and devices. 21 CFR 54.1	True
2	The term <i>covered clinical study</i> , as it relates to financial disclosure by investigators refers to all studies conducted in the US. 21 CFR 54.2	False
3	As related to financial disclosure, the term <i>covered clinical study</i> includes only those studies being submitted to the FDA in a marketing application or reclassification petition that the FDA or applicant relies on to establish effectiveness. 21 CFR 54.2	True
4	Sponsors of marketing applications submitted to the FDA are required to submit a list of all clinical investigators, who are full-time and part-time employees of the sponsor for each covered study. 21 CFR 54.4	True
5	The term <i>significant equity interest in the sponsor of a covered study</i> includes any ownership in stock or other financial interest that exceed \$ 10,000. 21 CFR 54.2	False
6	The US FDA's financial disclosure regulations applies only to investigators and sub-investigators. 21 CFR 54.2	False
7	An example of an investigator's proprietary interest in a tested product includes interests such as a agreement between the sponsor and investigator to provide the investigator with a bonus payment for study results that favorably support the intended indication for the product. 21 CFR 54.2	False
8	Clinical investigators who hold an investigational device exemption are not required to provide sponsors with adequate information to enable the sponsor to comply with the financial disclosure regulations. 21 CFR 54.4	False
9	Sponsors submitting marketing applications for drugs, biologics or devices are required to include Form FDA 3454, which attests to the absence of financial interests and arrangements for those investigators who provided such information to the sponsor. 21 CFR 54.4.	True
10	Applicants may discard records of clinical investigator financial disclosure one year following approval of an application. 21 CFR 54.6	False

Want More Information?

We hope you have enjoyed testing your GCP knowledge with this quiz.

We have more than 900 GCP flash cards covering all US GCP regulations for drugs, biologics and medical devices, as well as the international GCP requirements in the ICH GCP Guideline.

We also have on-line GCP tests that include 100 questions with feedback and 200 question GCP tests to evaluate GCP knowledge.

For more information about these products and services, please visit our on-line product catalog:
<http://RANINSTITUTE.TrainingCampus.Net> or call us at 813-929-9269.