



3-Minute GCP Quiz™ Human Subject Protection January, 2008

	Question	Answer
1	GCP requires all clinical research studies in human subjects to undergo initial and continuing review by an independent ethical committee known as an Institutional Review Board IRB or Independent Ethics Committee Review IEC.	<input type="radio"/> True <input type="radio"/> False
2	Submission of a final report by the investigator to the IRB is typically required by the sponsor of a study, yet it is not a GCP requirement.	<input type="radio"/> True <input type="radio"/> False
3	GCP requires the IRB or IEC to review, make recommendations for modification and issue final approval of the Investigator's Brochure for all clinical studies.	<input type="radio"/> True <input type="radio"/> False
4	GCP requires the protocol, protocol amendments, participant recruitment information such as advertising, the informed consent form and any other written information to be provided to participants of a clinical study to be both reviewed and approved by an IRB.	<input type="radio"/> True <input type="radio"/> False
5	The role of the clinical research coordinator in the informed consent process includes only those responsibilities delegated to him or her by the investigator. Further, GCP requires the documentation of all delegated responsibilities.	<input type="radio"/> True <input type="radio"/> False
6	Conducting a quarterly continuing review of research and providing a written statement to the sponsor that the IRB or IEC operates in compliance with GCP principles and applicable regulations are both GCP requirements of the IRB or IEC.	<input type="radio"/> True <input type="radio"/> False
7	GCP requires the investigator and his or her designees to ensure that the informed consent discussion and informed consent form include all required elements of informed consent and that voluntary, legal, written informed consent is obtained using the form approved by the IRB or IEC prior to the beginning of any study procedures. GCP further requires that subjects or their representatives are given adequate time to consider participation in the study.	<input type="radio"/> True <input type="radio"/> False
8	A partially competent adult patient who upon request does not strongly object or assent to participation in a clinical trial that might otherwise benefit the patient's health may be legally enrolled in a study, provided that a legally authorized representative and witness do give informed consent on behalf of the subject.	<input type="radio"/> True <input type="radio"/> False
9	A mentally competent adult subject is legally able to give his or her own informed consent to participate in a clinical trial without the presence of a witness.	<input type="radio"/> True <input type="radio"/> False
10	Assent applies only to subjects who are under the age of 18 in the US.	<input type="radio"/> True <input type="radio"/> 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 on February 15, 2008.

We have more than 950 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 offer Certification Preparation Packages for Coordinators, Investigators and Monitors.

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