



3-Minute GCP Quiz™

IRB Documentation

	ANSWERS	Answer
1	The FDA's regulations require investigators to submit a copy of Form FDA 1572 to the reviewing IRB for all studies conducted under an IND. <i>This is not contained in the FDA's regulations</i>	False
2	GCP does not permit the IRB to require an investigator to obtain continuing review any more often than four times each year. <i>This is not contained in the FDA's regulations</i>	False
3	Any revision to an informed consent form must be approved by the reviewing IRB prior to implementation in an approved study. <i>21 CFR 50.27, ICH GCP 4.8.2, ICH GCP 8.3.3</i>	True
4	According to the FDA's regulations, an IRB may approve or disapprove research using an expedited review process provided the research does not present any risk to subjects other than what may be typically encountered in daily activity. <i>The IRB may approve, but may not disapprove research using an expedited review process. 21 CFR 56.110</i>	False
5	Where required by local law, investigators are required to file a final report of study activity with the reviewing IRB. <i>ICH GCP 8.4.7</i>	True
6	According to GCP, the IRB should maintain a list of its members and their qualifications, and should provide that list to a sponsor or investigator upon request. <i>ICH GCP 3.2, 3.4</i>	True
7	The ICH GCP guideline requires the IRB to provide the investigator with written documentation of its decision(s) within 3 working days. <i>This is not contained in the ICH guideline.</i>	False
8	For studies conducted under the US IND regulations, the IRB is required to review the language and content required in HIPAA authorization statements. Click here for a valuable guideline from the US Department of Health and Human Services on HIPAA in Clinical Research.	False
9	Sponsors are required by GCP to obtain written verification of an IRB's decision to approve research prior to permitting the investigator to commence the study. <i>ICH GCP 8.2.7</i>	True
10	The ICH GCP guideline requires the investigator to include the name and signature of the chair of the reviewing IRB/IEC on the study Signature sheet defined in ICH GCP Guideline 8.3.24. <i>See ICH GCP 8.3.24.</i>	False

Want More Information?

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