
Practice Questions for SOCRA exam| 105 QUESTIONS| WITH COMPLETE SOLUTIONS

Which of the following is a disclosure of financial interests form? Correct Answer:

Which of the following is a certification of financial interest form? Correct Answer:

If the investigator did have financial arrangement with the sponsor, he/she would submit the following form: Correct Answer:

This form is submitted by sponsor to the FDA prior to the beginning of the drug trial Correct Answer: Investigational New Drug Application

In the top right corner, form have OMB number. What does it stand for? Correct Answer:

The form, which is submitted to the FDA to report an Adverse Event is Correct Answer:

Medical device adverse events/problems are reported via a form: Correct Answer:

What is FDA form 1571? Correct Answer:

21 CFR 312 deals with Correct Answer:

Investigational new drug means Correct Answer: A new drug or biological drug that is used in a clinical investigation

The immediate package of an investigational new drug intended for human use shall bear a label with the statement Correct Answer:

Which of the following is not listed on FDA form 1571: Correct Answer: a. name, address, phone number of the sponsor
b. a commitment not to start the clinical investigation until the IND is in effect
c. identification of the phase of the trial
d. approved informed consent document

"Any adverse drug experience that places the patient or subject, in the view of the investigator, at immediate risk of death from the reaction as it occurred" Is... Correct Answer: a. serious adverse drug experience
b. life threatening adverse drug experience
c. none of the above

What are the three main basic ethical principles of the Belmont Report? Correct Answer: 1. Respect for Persons
2. Beneficence
3. Justice

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Chao Zhang



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