* **Are there differences in FDA regulatory expectations for industry-sponsored trials as compared to sponsor-investigator trials?**

Yes/No

Answer: No

* **If you are a sponsor-investigator, do you have to submit a Form FDA 1572?**

Yes/No

Answer: Yes

* **Is Form FDA 3674 required for a research IND (not intended for commercial purposes) and accompanying clinical trial?**

Yes/No

Answer: Yes

* **Who signs and submits form FDA 1571?**

1. Sponsor
2. Investigator
3. Sponsor-Investigator
4. A &C

Answer: D

* **Only a clinician can be a principal Investigator on a clinical trial:**

True or False

Answer: False

**Which is a responsibility of a sponsor- investigator, name all that apply:**

A. Hiring contract research organization staff

B. Informing patients that the drugs are being used for investigational purposes

C. Ensuring initial and continuing review by an IRB

D. Registering and reporting results of applicable clinical trials to ClinicalTrials.gov

Answer: B, C, D

**Which of the following statements are true, name all that apply?**

A. S-I are required to report to FDA serious and unexpected adverse events.

B. S-I are required to submit to FDA clinical summary reports of all ongoing trials every 6 months.

C. S-I must permit FDA to have access to and copy and verify any records or reports made for the clinical trial.

D. S-I is responsible for monitoring their own study.

Answer: A, C, D

**Which of the following study types require the clinical investigator to sign a Form FDA 1572, Statement of Investigator?**

A. Drugs

B. Devices

C. Biologics

D. A & C

Answer: D

**Which of the following responsibilities can be delegated to the study coordinator?**

A. Study drug accountability

B. Physical exam

C. Regulatory submissions

D. A & C

Answer: D