

FDA Form 1572: Do You Know What You Are Signing?

By Norman M. Goldfarb

In 2006, clinical investigators signed 27,044 instances of FDA Form 1572 – Statement of Investigator.¹ In this form, the investigator provides important information and makes legal commitments to the FDA. But, how many investigators read the form? How many remember what they read a month later, when the study is getting underway?

Investigators can use the following quiz for self-evaluation. Study sponsors and research sites can use it as a training tool. The questions and answers apply only to Form 1572 and not other laws, regulatory requirements, and guidances. Answers are on the next page.

1572 Quiz

- | | | |
|--|------|-------|
| 1. The investigator must sign a Form 1572 for any clinical study that involves more than minimal risk to the subjects. | True | False |
| 2. The investigator must be an "expert" in clinical investigation of the study drug for the use under investigation. | True | False |
| 3. The investigator must obtain approval from the sponsor before changing the protocol. | True | False |
| 4. The investigator must personally participate in the informed consent process. | True | False |
| 5. The investigator must comply with applicable federal regulations. | True | False |
| 6. The investigator must provide the name and address of the study's central clinical lab, if any. | True | False |
| 7. The investigator must ensure that anyone assisting in the study complies with applicable regulatory requirements. | True | False |
| 8. The investigator is responsible for compliance by the central IRB, if any, with 21 CFR Part 56 – Institutional Review Boards. | True | False |
| 9. The investigator must read and understand the Investigator's Brochure before starting the clinical trial. | True | False |
| 10. Making a false statement on a Form 1572 is a criminal offense. | True | False |

Reference

1. Search on 1/30/07 at <http://www.accessdata.fda.gov/scripts/cder/bmis/>

Author

Norman M. Goldfarb is Managing Director of First Clinical Research LLC, a provider of clinical research best practices information, consulting and training services. Contact him at 1.650.465.0119 or ngoldfarb@firstclinical.com.

1572 Answers

- 1. The investigator must sign a Form 1572 for any clinical study that involves more than minimal risk to the subjects.**

False. The investigator must sign a 1572 for Phase I, II and III studies that are under the supervision of the FDA. Phase IV studies are excluded, as well as studies that are not part of an Investigational New Drug (IND) application. Risk is not a factor.

- 2. The investigator must be an "expert" in clinical investigation of the study drug for the use under investigation.**

True. The investigator must attach a curriculum vitae or other documentation demonstrating that this qualification is met.

- 3. The investigator must obtain approval from the sponsor before changing the protocol.**

False. Notification is required, but not approval. Notification is not required if the change is made to protect the safety, rights or welfare of the subjects.

- 4. The investigator must personally participate in the informed consent process.**

False. The investigator must "personally conduct or supervise the described investigation(s)" No mention is made of informed consent. There is no requirement that "supervision" requires the investigator's presence.

- 5. The investigator must comply with applicable federal regulations.**

False. The investigator is only required to comply with 21 CFR 312 and the informed consent requirements in 21 CFR 50 and 56.

- 6. The investigator must provide the name and address of the study's central clinical lab, if any.**

True. The investigator must provide the name and addresses of all clinical labs that test his/her subjects' specimens.

- 7. The investigator must ensure that anyone assisting in the study complies with applicable regulatory requirements.**

False. The investigator must ensure that they are informed of their obligations in the first five of the nine listed commitments. Record retention, for example, is not included.

- 8. The investigator is responsible for compliance by the central IRB, if any, with 21 CFR Part 56 – Institutional Review Boards.**

True. The investigator has this responsibility, even with central IRBs selected and paid by the study sponsor.

- 9. The investigator must read and understand the Investigator's Brochure before starting the clinical trial.**

False. The investigator must read and understand the document before signing Form 1572.

- 10. Making a false statement on a Form 1572 is a criminal offense.**

False. The offense is criminal only if the false statement is willful. However, signing a document that includes a false statement without reading it is willful conduct and could be interpreted as "willful ignorance" in making a false statement.