

## Summary of FDA Requirements For Investigators Who Are Also Considered Sponsors of New Drugs

This document provides an overview of the [Food and Drug Administration](#) (FDA) requirements for Sponsors with Investigational New Drugs (INDs). The [IRB sponsor- investigator mandatory training](#) provides additional information for new sponsor-investigators.

For detailed descriptions, consult the referenced [FDA regulation](#).

FDA expectations regarding appropriate delegation, supervision, and training for personnel involved in clinical investigations is described in the *FDA Guidance for Industry: Investigator Responsibilities-Protecting the Rights, Safety, and Welfare of Study Subjects*.

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf>

### **Major Responsibilities of Sponsors with IND Studies**

Enter the Code of Federal Register (CFR) citation in the [FDA Title 21 Data Base](#) for details.

1. Submit IND application, form 1571 and other required documents to FDA. (21 CFR 312.23)
2. Label the investigational drug in accordance with FDA regulations. (21 CFR 312.6)
3. Limit promotion. If any promotion is done, it must be done in accordance with IRB and FDA requirements. (21 CFR 312.7)
4. Select qualified investigators based on training and experience. (21 CFR 312.53)
5. Ship investigational drugs only to investigator(s) participating in the investigation. (21 CFR 312.53)
6. Obtain FDA Form 1572 from the investigator(s). (21 CFR 312.53)
7. Obtain a written statement that the investigator(s) will conduct the study as outlined in the protocol. (21CFR 312.53)
8. Obtain relevant financial information from the investigator(s). (21 CFR 312.53)
9. Select a monitor to oversee the progress of the investigation. (21 CFR 312.53)
10. Comply with FDA regulations regarding emergency use. (21 CFR 312.54)
11. Keep investigator(s) informed on the safety and effectiveness of the drug. (21 CFR 312.55)
12. Monitor the progress of all IND investigations. (21 CFR 312.56)
13. Terminate investigator(s) participation when investigator(s) fails to follow protocol. (21 CFR 312.56)
14. Review and evaluate the evidence relating to the safety and effectiveness of the drug as it is obtained from each investigator(s). (21 CFR 312.56)
15. Send safety reports to FDA according to the [2010 final rule](#), Investigational New Drug Safety Reporting Requirements for human drug and biologics (21 CFR 312.32) and for Bioavailability and Bioequivalence Studies (21 CFR 320).
16. Discontinue the study if the investigational drug presents an unreasonable and significant risk to subjects. (21 CFR 312.56)
17. Notify the FDA, IRB and the investigator(s) if the study is discontinued. (21 CFR 312.56)

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18. Maintain adequate records showing the receipt, shipment, or other disposition of the investigational drug. (21CFR 312.57)
19. Maintain complete and accurate records of payments made to clinical investigator(s). (21 CFR 312.57)
20. Permit and facilitate monitoring and auditing by the IRB or inspection by federal or state regulatory agencies (e.g. FDA or Drug Enforcement Administration for investigations of controlled substances) as appropriate. (21CFR 312.58)
21. Assure that investigator(s) return all unused investigational drugs. (21 CFR 312.59)
22. Require investigator(s) to maintain adequate drug records (21 CFR 312.62)
23. Require investigator(s) to keep case histories on each individual administered the investigational drug or employed as a control in the investigation. (21 CFR 312.62)
24. Collect reports (financial, progress, safety, and final report) from investigator(s). (21 CFR 312.64)
25. Require investigator(s) to meet local IRB requirements. (21 CFR 312.66)
26. Require investigator(s) to store the investigational drug in a secure area. (21 CFR 312.69)
27. Register the study at ClinicalTrials.gov (<https://clinicaltrials.gov/>) per the Food and Drug Administration Amendments Act (FDAAA) of 2007 (Public Law 110-85). For requirements and instructions on registering trials see the information page at <http://clinicaltrials.gov/ct2/manage-recs/fdaaa>. To obtain access to the University of Kentucky organizational account on ClinicalTrials.gov see guidance at <https://www.research.uky.edu/office-sponsored-projects-administration/clinicaltrialsgov>.
28. Comply with FDA regulations on electronic records and electronic signatures (21 CFR 11). <http://www.fda.gov/RegulatoryInformation/Guidances/ucm125067.htm>
29. Comply with FDA financial disclosure requirements (21 CFR 54). <https://www.fda.gov/downloads/regulatoryinformation/guidances/ucm341008.pdf>

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