

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

This document provides an overview of the [Food and Drug Administration](#) (FDA) requirements for sponsors of device research trials. The [IRB sponsor- investigator mandatory training](#) provides additional information for new sponsor-investigators.

This overview is divided into two sections:

- 1) responsibilities of sponsors for significant risk device studies; *and*
- 2) responsibilities of sponsors for nonsignificant risk device studies.

For detailed descriptions consult the referenced [FDA regulation](#) or the FDA's [IDE Responsibilities Website](#).

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 Significant Risk Device Studies

1. Submit a complete IDE application to FDA. (21 CFR 812.20)
2. Submit the investigational plan and report of prior investigations (21 CFR 812.25 and 21 CFR 812.27) to the IRB at each institution where the investigation is to be conducted.
3. Obtain FDA & IRB approval for IDE. (21 CFR 812.42)
4. Select investigator(s) with appropriate training and experience. (21 CFR 812.43)
5. Obtain a signed agreement from the investigator with the required FDA documents. (21 CFR 812.43)
6. Select a monitor in accordance with FDA regulations. (21 CFR 812.43)
7. Ship investigational devices only to qualified investigators. (21 CFR 812.43)
8. Supply the investigator(s) with copies of the investigational plan and copies of prior device investigations. (21 CFR 812.45)
9. Label the device in accordance with FDA labeling provisions of the IDE regulation and with the statement "CAUTION - Investigational Device. Limited by Federal (or United States) law to investigational use." (21 CFR 812.5)
10. Ensure that investigator(s) are complying with FDA, IRB and sponsor requirements. (21 CFR 812.46)
11. Conduct an evaluation of unanticipated adverse events and terminate the study if necessary. (21 CFR 812.46)
12. Resume terminated studies only after receiving approval from the FDA and IRB. (21 CFR 812.46)

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

13. Ensure that each investigator obtains consent for each subject before being enrolled in the study. ([21 CFR 50](#))
14. Maintain accurate and complete records in accordance with FDA regulations. (21 CFR 812.140)
15. Permit and facilitate monitoring and auditing by the IRB or inspection by federal or state regulatory agencies as appropriate. (21 CFR 812.145)
16. Provide required reports to IRB, investigator(s) and FDA in a timely manner. (21 CFR 812.150)
17. Limit promotion of the device. Commercialization, promotion, and misrepresentation of an investigational device and prolongation of the study are prohibited. (21 CFR 812.7)
18. Comply with federal regulations regarding emergency use. (21 CFR 812.47)
19. Register the study at 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 <http://www.ccts.uky.edu/BRIC/ClinicalTrialsgov.aspx>.
20. Comply with FDA regulations on electronic records and electronic signatures (21 CFR 11). <http://www.fda.gov/RegulatoryInformation/Guidances/ucm125067.htm>
21. Comply with FDA financial disclosure requirements (21 CFR 54). <http://www.fda.gov/RegulatoryInformation/Guidances/ucm126832.htm>

Major Responsibilities of Sponsors with Nonsignificant Risk Device Studies –

Nonsignificant risk device sponsors must comply with the abbreviated IDE requirements under [21 CFR 812.2 \(b\)](#):

1. Select investigator(s) with appropriate training and experience. (21 CFR 812.43)
2. Select a monitor in accordance with FDA regulations. (21 CFR 812.43)
3. Ship investigational devices only to qualified investigators. (21 CFR 812.43)
4. Supply the investigator(s) with copies of the investigational plan and copies of prior device investigations. (21 CFR 812.45)
5. Label the device in accordance with FDA labeling provisions of the IDE regulation and with the statement "CAUTION - Investigational Device. Limited by Federal (or United States) law to investigational use". (21 CFR 812.5)
6. Obtain IRB approval of the investigation as a nonsignificant risk device study and maintain IRB approval during the investigation. (21 CFR 812.2)
7. Ensure that investigator(s) are complying with FDA, IRB and sponsor requirements. (21 CFR 812.46)

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

8. Conduct an evaluation of unanticipated adverse events and terminate the study if necessary. (21 CFR 812.46)
9. Resume terminated studies only after receiving approval from the IRB and if terminated due to an unanticipated adverse device effect, also obtain FDA approval to resume the study. (21 CFR 812.46)
10. Ensure that each investigator obtains consent for each subject unless the IRB grants a waiver under 21CFR56.109(c).
11. Ensure that each investigator maintains accurate and complete records in accordance with FDA regulations and reports the results to the appropriate parties. (21 CFR 812.140 & 21 CFR 812.150)
12. Permit and facilitate monitoring and auditing by the IRB or inspection by federal or state regulatory agencies as appropriate. (21 CFR 812.145)
13. Limit promotion of the device. Commercialization, promotion, and misrepresentation of an investigational device and prolongation of the study are prohibited. (21 CFR 812.7)
14. Register the study at 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 <http://www.ccts.uky.edu/BRIC/ClinicalTrialsgov.aspx>.
15. Comply with FDA regulations on electronic records and electronic signatures (21 CFR 11). <http://www.fda.gov/RegulatoryInformation/Guidances/ucm125067.htm>
16. Comply with FDA financial disclosure requirements (21 CFR 54). <http://www.fda.gov/RegulatoryInformation/Guidances/ucm126832.htm>

Revised 11/29/12

J:\Master Outreach Documents\Survival Handbook\D - Guidance-Policy-Educational\45-Revised_IDE_Document.doc