

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

This is an overview of the Food and Drug Administration (FDA) requirements for Sponsors with an Investigational Device Exemption (IDE). The overview is divided into two sections: Responsibilities of Sponsors for Significant Risk Device Studies & Responsibilities of Sponsors for Nonsignificant Risk Device Studies. The overview cites the appropriate FDA regulation for each item. Before using the overview, review the federal regulations {21 CFR 812.3(m)} to determine if the device is a Significant Risk or a Nonsignificant Risk Device.

**This document is only a summary of the FDA's requirements for Sponsors with an IDE. Please review the federal regulations before performing any sponsor's duties. If you are the sponsor and the investigator for the device, you must meet the requirements for the sponsor and the investigator. Additional information is available at the FDA website: <http://www.fda.gov/>**

### Major Responsibilities of Sponsors with Significant Risk Device Studies

1. Obtain FDA & IRB approval for IDE. (21 CFR 812.42)
2. Select investigator(s) with appropriate training and experience. (21 CFR 812.43)
3. Select Monitor in accordance with FDA regulations. (21 CFR 812.43)
4. Ship investigational devices only to qualified investigators. (21 CFR 812.43)
5. Obtain a signed agreement from the investigator with the required FDA documents. (21 CFR 812.43)
6. Supply the investigator(s) with copies of the investigational plan and copies of prior device investigations. (21 CFR 812.45)
7. Ensure that investigator(s) are complying with FDA, IRB and sponsor requirements. (21 CFR 812.46)
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 FDA and IRB. (21 CFR 812.46)
10. Maintain accurate and complete records in accordance with FDA regulations. (21 CFR 812.140)
11. Provide required reports to IRB, investigator(s) and FDA in a timely manner. (21 CFR 812.150)
12. Label the device in accordance with FDA requirements. (21 CFR 812.5)
13. Limit promotion of the device. If any promotion is done, it must be done in accordance with IRB and FDA requirements. (21 CFR 812.7)
14. Comply with federal regulations regarding emergency use. (21 CFR 812.47)

## Major Responsibilities of Sponsors with Nonsignificant Risk Device Studies

1. Select investigator(s) with appropriate training and experience. (21 CFR 812.43)
2. Select 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 requirements. (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)
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 FDA and IRB. (21 CFR 812.46)
10. Ensure that each investigator obtains consent for each subject unless the IRB grants a waiver. (21 CFR 812.2) Please note that federal regulations may permit a waiver of informed consent. (21 CFR 50.23 [a – c]; 21 CFR 23(d); 21 CFR 50.24)
11. Maintain accurate and complete records in accordance with FDA regulations and report the results to the FDA, IRB and investigators. (21 CFR 812.140 & 21 CFR 812.150)
12. 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)
13. Limit promotion of the device. If any promotion is done, it must be done in accordance with IRB and FDA requirements. (21 CFR 812.7)

Handout prepared by Joe Brown, University of Kentucky Office of Research Integrity.  
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