

IDE Sponsor Reporting Requirements

Submission	Timing
Unanticipated Adverse Device Effects	The FDA and all participating investigators must be notified within 10 working days of the sponsor's receipt of notice All reviewing IRBs must be notified according to their policies and procedures
Withdrawal of IRB Approval	The FDA, all reviewing IRBs and all participating investigators must be notified within 5 working days of the sponsor's receipt of notice
Withdrawal of FDA Approval	All reviewing IRBs and participating investigators must be notified within 5 working days of the sponsor's receipt of notice from FDA
Current Investigator List	The FDA must be submitted 6 months after FDA acceptance of the IDE application. The FDA must be provided with an updated list every 6 months
Progress Reports	The FDA and all reviewing IRBs must be provided with progress reports at regular intervals but no less than yearly
Notice of Device Recall or Disposition	The FDA and all reviewing IRBs must be notified within 30 working days of the sponsor making such request
Final Report	The FDA and all reviewing IRBs must be notified within 30 working days of completion or termination of the investigation (6 months For Non-significant Risk device studies)
Failure to Obtain Informed Consent	The FDA must be notified within 5 working days of the sponsor's receipt of notice
Unexpected Significant Risk Device Determination	The FDA must be notified if an IDE study initially submitted as a non-significant risk device study is determined by the reviewing IRB to be a significant risk device study. Notification to FDA must be made within 5 working days after the sponsor learns of this determination

Unanticipated Adverse Device Effects: A sponsor who conducts an evaluation of an unanticipated adverse device effect under 812.46(b) must report the results of such evaluation to FDA and to all reviewing IRB's and participating investigators within 10 working days after the sponsor first receives notice of the effect. The results of the evaluation must be reported in

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writing to FDA on FDA Form 3500A. Thereafter the sponsor shall submit such additional reports concerning the effect as FDA requests.

Withdrawal of IRB Approval: Notify FDA and all reviewing IRB's and participating investigators of any withdrawal of approval of an investigation or a part of an investigation by a reviewing IRB within 5 working days after receipt of the withdrawal of approval.

Withdrawal of FDA Approval: Notify all reviewing IRB's and participating investigators of any withdrawal of FDA approval of the investigation, and must do so within 5 working days after receipt of notice of the withdrawal of approval.

Current investigator List: Submit to FDA, at 6-month intervals, a current list of the names and addresses of all investigators participating in the investigation. The sponsor must submit the first such list 6 months after FDA approval.

Progress Reports: At regular intervals, and at least yearly, a sponsor must submit progress reports to all reviewing IRB's. In the case of a significant risk device, a sponsor must also submit progress reports to FDA. A sponsor of a treatment IDE must submit semi-annual progress reports to all reviewing IRB's and FDA in accordance with 812.36(f) and annual reports in accordance with this section.

Recall and Device Disposition: Notify FDA and all reviewing IRB's of any request that an investigator return, repair, or otherwise dispose of any units of a device. Such notice must occur within 30 working days after the request is made and shall state why the request was made.

Final Report: In the case of a significant risk device, the sponsor shall notify FDA within 30 working days of the completion or termination of the investigation and must submit a final report to FDA and all reviewing the IRB's and participating investigators within 6 months after completion or termination. In the case of a device that is not a significant risk device, the sponsor shall submit a final report to all reviewing IRB's within 6 months after termination or completion.

Failure to Obtain Informed Consent: Submit to FDA a copy of any report by an investigator under paragraph (a)(5) of this section of use of a device without obtaining informed consent, within 5 working days of receipt of notice of such use.

Significant Risk Device Determinations: If an IRB determines that a device is a significant risk device, and the sponsor had proposed that the IRB consider the device not to be a significant risk device, the sponsor must submit to FDA a report of the IRB's determination within 5 working days after the sponsor first learns of the IRB's determination.

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Other: A sponsor must, upon request by a reviewing IRB or FDA, provide accurate, complete, and current information about any aspect of the investigation.