

IDE Investigator Reporting Requirements

An Investigator must prepare and submit the following complete, accurate, and timely reports:

Submission	Timing
Unanticipated Adverse Device Effects	The sponsor and reviewing IRB must be notified within 10 working days after the investigator first learns of the effect
Withdrawal of IRB Approval	The sponsor must be notified within 5 working days
Progress Reports	The sponsor, monitor and reviewing IRB must be provided with progress reports at regular intervals but no less than yearly
Deviations from the Investigational Plan	The sponsor and reviewing IRB must be notified of any deviation from the investigational plan to protect the life or physical well-being of a subject in an emergency. Such notice should be given ASAP but no later than 5 working days after the emergency occurred
Failure to Obtain Informed Consent	The sponsor and reviewing IRB must be notified within 5 working days after the device was used without obtaining informed consent
Final Report	The sponsor and reviewing IRB must be notified within 3 months of completion or termination of the investigation

Unanticipated adverse device effects: Submit to the sponsor and to the reviewing IRB a report of any unanticipated adverse device effect occurring during an investigation as soon as possible, but in no event later than 10 working days after the investigator first learns of the effect.

Withdrawal of IRB Approval: Report to the sponsor, within 5 working days, a withdrawal of approval by the reviewing IRB of the investigator's part of an investigation.

Progress Reports: Report on the investigation to the sponsor, the monitor, and the reviewing IRB at regular intervals, but in no event less often than yearly.

Deviations from the Investigational Plan: Notify the sponsor and the reviewing IRB (see 56.108(a) (3) and (4)) of any deviation from the investigational plan to protect the life or physical well-being of a subject in an emergency. Such notice must be given as soon as possible, but in no event later than 5 working days after the emergency occurred. Except in such an emergency, prior approval by the sponsor is required for changes in or deviations from a plan, and if these changes or deviations may affect the scientific soundness of the plan or the rights,

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safety, or welfare of human subjects, FDA and IRB in accordance with 812.35(a) also is required.

Failure to Obtain Informed Consent: If an investigator uses a device without obtaining informed consent, the investigator must report such use to the sponsor and the reviewing IRB within 5 working days after the use occurs.

Final Report: Within 3 months after termination or completion of the investigation or the investigator's part of the investigation, submit a final report to the sponsor and the reviewing IRB.

Other: Request by a reviewing IRB or FDA, provide accurate, complete, and current information about any aspect of the investigation.