

US IDE Sponsor Obligations Checklist

21 CFR 812 Subpart C

Under 21 CFR 812.18(a), the US sponsor of record owns every Part 812 obligation for an IDE study: the application, FDA correspondence, investigator oversight, monitoring, and safety reporting. A company outside the United States cannot hold this role itself.

The Rule, Quoted

“In addition to complying with other requirements of this part, a person who imports or offers for importation an investigational device subject to this part shall be the agent of the foreign exporter with respect to investigations of the device and shall act as the sponsor of the clinical investigation, or ensure that another person acts as the agent of the foreign exporter and the sponsor of the investigation.” — 21 CFR 812.18(a)

“A foreign company cannot sponsor an IDE; the company must have a U.S. agent who acts as the sponsor.” — FDA, FAQs About Investigational Device Exemption

Why a CRO Cannot Absorb These Obligations

21 CFR Part 312, the parallel framework for drug studies, lets a sponsor transfer obligations to a contract research organization in writing at 21 CFR 312.52. Part 812, the device framework, has no equivalent provision. FDA's own compliance program for inspecting sponsors, CROs, and monitors treats an entity holding transferred obligations the same as a sponsor, only for what it actually took on in writing: “the term ‘sponsor’ also refers to any entity to whom one or more of the obligations of the sponsor has been transferred in writing” (FDA Compliance Program 7348.810). An obligation never specified in that writing stays with the sponsor of record.

How ADB Holds Them

ADB Consulting and CRO Inc. acts as the US sponsor of record under 21 CFR 812.18(a) for non US medical device companies conducting IDE studies, from \$2,495 initiation for non-significant-risk studies and from \$3,500 initiation for significant-risk studies, with an optional \$4,500 Sponsor Readiness Assessment credited in full within 90 days for sponsors who want a scoping review first. See adbccro.com/us-sponsor for the full tier structure.

The Checklist

Every row is an obligation that attaches to the sponsor by regulation. Execution of a task can be assigned by written agreement; accountability to FDA for the obligation itself stays with whoever holds the sponsor of record designation. Use the last column to note which obligations your current structure already covers.

OBLIGATION	SECTION	WHAT IT MEANS IN PRACTICE	WHO TYPICALLY HOLDS IT
Submit the IDE application and supplements	812.20, 812.35	The sponsor files the original IDE application with FDA and submits every amendment or supplement as the protocol or device changes.	US Sponsor
Investigational plan and report of prior investigations	812.25, 812.27	The sponsor prepares the investigational plan (objectives, protocol, risk analysis, monitoring procedures) and compiles the prior investigation reports supporting the study.	US Sponsor
Act as agent and sponsor for imported devices	812.18(a)	Whoever imports the investigational device into the United States must either act as the foreign exporter's agent and the study sponsor, or ensure another person holds both roles.	US Sponsor
General responsibilities of sponsors	812.40	The sponsor selects qualified investigators, supplies the information needed to conduct the study properly, ensures monitoring, and maintains required records.	US Sponsor
Obtain FDA and IRB approval before starting	812.42	No subject may be enrolled and no device shipped for the study until FDA (for significant risk studies) and the reviewing IRB have both approved the investigation.	US Sponsor
Select qualified investigators and monitors; obtain signed investigator agreements	812.43	The sponsor selects investigators qualified by training and experience, selects qualified monitors, and obtains a signed agreement from each investigator before shipping the device.	US Sponsor
Inform investigators (investigational plan, device information, new information)	812.45	The sponsor supplies every investigator with the investigational plan and a current investigator's brochure, and keeps them informed of new safety or effectiveness observations as the study proceeds.	US Sponsor

OBLIGATION	SECTION	WHAT IT MEANS IN PRACTICE	WHO TYPICALLY HOLDS IT
Monitor the investigation; secure compliance; evaluate unanticipated adverse device effects	812.46	The sponsor monitors investigator performance, acts (including halting the study) if an investigator fails to comply with the agreement or protocol, and evaluates and reports unanticipated adverse device effects.	US Sponsor
Device labeling; prohibition of promotion and commercialization	812.5, 812.7	Investigational devices must carry FDA required investigational use labeling, and the sponsor may not promote, test market, or commercialize the device as though already cleared or approved.	US Sponsor
Sponsor records: correspondence, shipment and disposition, investigator agreements, adverse effects	812.140(b)	The sponsor maintains records of all correspondence with FDA and investigators, device shipment and final disposition, signed investigator agreements, and adverse device effect reports, available for FDA inspection.	US Sponsor
Sponsor reports: UADE within 10 working days, withdrawal of IRB or FDA approval, current investigator list, progress and final reports, recall and device disposition	812.150(b)	The sponsor reports unanticipated adverse device effects to FDA and all reviewing IRBs within 10 working days, and submits withdrawal of approval notices, periodic progress reports, a current investigator list, and final and recall and disposition reports on FDA's schedule.	US Sponsor

"Who typically holds it" assumes a non US manufacturer using a contracted US sponsor of record. Execution can be delegated by written agreement; accountability to FDA cannot (FDA Compliance Program 7348.810).

Reviewed October 17, 2026 by ADB's regulatory team. Not legal advice; obligations summarized from 21 CFR 812 as of October 17, 2026.