Drug/Device Accountability

Drug / Device Accountability

Requirements

- Drug/Device Shipment and Receipt Records
- Drug/Device Accountability Log
- Most recent version of Investigator Brochure or Device Manual

Tips / Additional Information

If the drug/device shipment, receipt, and accountability are managed by research pharmacy, indicate this in a note-to-file.

Refer to ResearchGo for drug and device accountability logs.

The Investigator's Brochure or Device Manual provides clinical and non-clinical data on an investigational new drug or device. Updated versions of the Investigator's Brochure or Device Manual should be submitted to the IRB.

If the drug is marketed, a package insert is an appropriate alternative for the Investigator's Brochure. For marketed devices, basic product information is an appropriate alternative for the Device Manual.

Please click here for more information about the Investigational Pharmacy.

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