

CALGB Data Audit

Pharmacy

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- NCI Drug Accountability Record Form (DARF)
- **No “Whiteout” or “Mark-overs”**
- Notation for drug received and dispensed
- Shipping invoices kept for inspection
- Shelf supply matches balance on DARF
- Drug used ONLY for protocol patients

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- Commercial drug should **NOT** be used for protocol patients when drug supplied
- Drug in secure location with limited access
- NCI Approval prior to transfer of drug from one protocol to another
- Return of drug to NCI on closed studies
PROMPTLY – within 3 months of closure

DARFs

- Use only for receipts from NCI/supplier and for drug dispensed to patients
- Do NOT enter patient returned drug
- Utilize a generic destruction log for patient returned drug
- Designate if control or satellite record

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- Review 1-5 drug logs and inventory for investigational drugs
- Review unannounced patient on protocol utilizing investigational drug
- Make sure investigational pharmacist is available day of audit for drug audit
- Prevention – internally audit your pharmacy every 3-4 months