



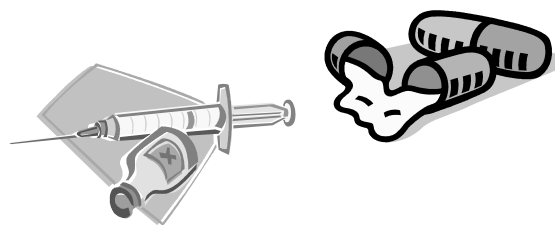
## Pharmacy

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*CALGB Audit Preparation Workshop, June 2007*

*For CALGB Participants Only*

## Investigational Drugs for CALGB studies



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### Ordering Investigational Drugs

- The Division of Cancer Treatment and Diagnosis (DCTD) of NCI supplies majority of INDs
- INDs shipped from Pharmaceutical Management Branch (PMB)
- Shipped directly to institution or site where drug will be prepared and administered
- Refer to drug information section of the protocol to identify the supplier

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### NCI Clinical Drug Request

- Need Investigator name, NCI # and signature
- Person ordering IND and phone #
- Fax #
- Date order sent and date needed
- NCI protocol number
- Drug name, NSC #, strength and dose, and quantity ordered

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## Emergency Supply

- Fax Clinical Drug Request directly to NCI at 301-480-4612 prior to noon eastern time for next day delivery
- Include express courier name and account number
- Follow-up telephone call to 301-496-5725 is highly recommended
- Rush orders done only in emergency situations

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## Receiving INDs



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## Receiving Protocol INDs

- Drug shipments accompanied by drug receipts or shipment documents
- Verify for accuracy or damage to shipment
- File invoices or receipts for source documentation at audit time

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## Storage



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## Handling INDs

- Label drug container with protocol # and drug name
- Kept in secure, limited-access storage area
- Separate storage container for each IND
- Store separately from commercial supplies of medicines

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## Handling INDs

- FDA recommends the pharmacy department, whenever possible, be responsible for drug receipt, storage, accountability, and preparation of INDs
- Daily temperature log should be kept for refrigerator and freezer

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## Drug Accountability Record Form (DARF)



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## Completing DARFs

- DARFs (Drug Accountability Record Forms)
- Separate DARF for each drug in the protocol
- Each study should have their own DARF
- Separate DARF for each dosage of a medicine, ie; 100mg, 200mg and 500mg
- All drug supplies received from NCI noted

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## Return of IND

- Return to Supplier:
  - Study completed or discontinued
  - Drug is outdated/expired
  - Obvious excess in inventory
  - Drug is damaged (loss of refrigeration)
- Use traceable mail and package drugs securely to prevent breakage

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## Return of IND

- Return to NCI at room temperature
- Complete Return Drug List Form
- Keep Return Drug forms for audits
- Subtract amount returned from DARF balance

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## Transfer of INDs

- Transfer from one active protocol to another DCTD approved protocol
- If protocol closes and another protocol utilizes the same IND and formulation
- Requires NCI approval by phone 301-496-5725 and in writing

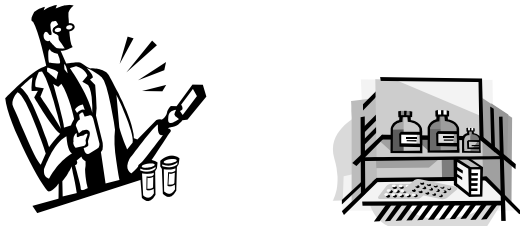
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## NEVER Transfer INDs

- To commercial use
- Replace IND with commercial drug
- Blinded study agents between protocols
- Borrowing of study drug
- Transfer between satellites

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## Pharmacy Audit



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## Pharmacy

- 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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## Pharmacy

- 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

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## 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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## Pharmacy

- 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

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"Honey, when you left for the office this morning, you were a happy, enthusiastic, vibrant 25 year old! Do you want to talk about it?"