

PHARMACY AUDIT ISSUES

Order, Receipt, Storage, Administration, Return,
Destruction

James Sumka, MSc, PharmD
Saint Barnabas Cancer Center
Dept. of Clinical Research
Livingston, NJ



ORDER Of Medication

- Appropriate Order Form Fax / e-mail
- IVRS – Inventory Adjustment
- CONTACT Person or Phone Number



RECEIPT Of Study Meds

- LOOK AT INVOICE – IS IT YOURS?
- If So, SIGN and DATE (Time)
- Some require IVRS/FAX
- Note Receipt on Accountability Sheet
- Label Med (Ready for Storage)
- Caution If Signs of Breakage



STORAGE of Study Meds

- Room Temp: Locked/Labeled Cabinets
- Fridge: Secured Section
- Label Containers: Study & Med Info
- Separate Pts Stock if Patient Specific
- Maintain Daily Temp Log
- JCAHO now looking for Alarms



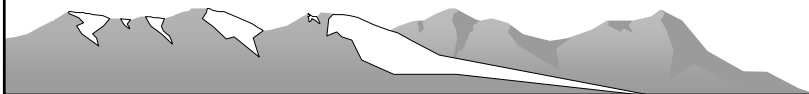
Study Med ADMINISTRATION

- As Dictated By Protocol
- **Some** Studies Allow For Overfill
- Advisable To Wear Gloves
- Coordinate w/ Order & Accountability Log
- Policy for Partial/Empty Vials & PO Meds
- IVRS Access
- Follow-thru (Numbered Vials/Lots)



Study Med RETURN

- NCI – Fill Out Return Form & Ship
- Pharma – Monitor will inventory 1st
- Form Will Serve as Invoice – Keep Copy
- Coordinate with Accountability Log
- Package Securely; Note Contents



Study Med DESTRUCTION

- Damaged, Empty or Partial Vials
- Have Copy of Destruction Policy
- Have Copy of Hazardous Waste Company
- Have Name/Number of Safety Officer



SAFETY

- Always Think Safety
- Always Use Gloves
- If Broken Glass, Open in Hood

