Center for Clinical and Translational Science

INVESTIGATIONAL PRODUCT ACCOUNTABILITY LOG INSTRUCTIONS

PURPOSE

Documentation of study product receipt, disposition and accountability.

HOW TO USE

- Complete the form header by adding the study title, IRB number and current investigator information.
- Upon receipt of investigational product, inventory the shipment to confirm that the information on the packing slips matches the contents. Complete the Drug Receipt portion of the log as follows:
    - The study team member receiving the investigational product enters the date of receipt and their initials as well as the lot number, expiration date and quantity.
- As investigational product is dispensed, the Drug Use portion of the log should be updated as follows:
    - The study team member dispensing the drug enters the date the drug was dispensed, their initials, the participant ID code, quantity dispensed and any comments.
- Unused investigational product should be disposed of in accordance with the study protocol. As this determination is made, the corresponding action should be recorded in the Drug return/Destruction portion of the log as follows:
    - The responsible study team member should identify what will be done with the unused drug, whether it will be returned or destroyed, and provide a reason (for either return or destruction) as well as the quantity, date of return or destruction, obtain authorization for the action and initial the log themselves as the team member taking the action.

GOOD PRACTICE RECOMMENDATIONS

- Verify that investigational product received is within an appropriate expiration date for the study
- File all packing slips, certificates of analysis, etc. received with the shipment
- Store investigational product in a secure environment
- Ensure that investigational product is stored at the appropriate temperature and maintain a daily storage area temperature log.
- File all copies of drug return shipment slips and disposal instructions.
- Be sure to customize the template to make it study specific.