

INVESTIGATIONAL DEVICE ACCOUNTABILITY LOG INSTRUCTIONS

PURPOSE

Documentation of investigational device 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 device, inventory the shipment to confirm that the information on the packing slip matches the contents. Complete the Device Receipt portion of the log as follows:
 - The study team member receiving the investigational device enters the date of receipt and their initials as well as the model number, serial number, lot # and quantity.
- As the investigational device is dispensed, the Device Use portion of the log should be updated as follows:
 - The study team member dispensing the device enters the date the device was dispensed, their initials, the participant's ID code, quantity dispensed and any comments.
- Unused investigational devices should be disposed of in accordance with the study protocol. As this determination is made, the corresponding action should be recorded in the Device return/Destruction portion of the log as follows:
 - The responsible study team member should identify what will be done with the unused device, 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 device received is within an appropriate expiration date for the study.
- File all packing slips, certificates of analysis, etc. received with the shipment.
- Store the investigational device in a secure environment.
- Insure that the investigational device is stored at the appropriate temperature and maintain a daily storage area temperature log, as appropriate.
- File all copies of device return shipment slips and disposal instructions.
- Be sure to customize the template to make it study-specific.