

**PRINCIPAL INVESTIGATOR
INVESTIGATIONAL DRUG/DEVICE AUDIT FORM**

PROJECT NUMBER: _____

DATE OF AUDIT: _____

PROJECT TITLE: _____

YES	NO	DOES THE PRINCIPAL INVESTIGATOR MAINTAIN AN INVESTIGATIONAL DRUG/DEVICE LOG WHICH INCLUDES THE FOLLOWING:
		1. Name of Drug or Device
		2. Dosage Form and Strength
		3. Manufacturer or Other Source
		4. Date of Receipt of the Drug or Device
		5. Quantity Received
		6. Expiration Date
		7. Control or Lot Number
		8. Protocol Number
		9. Date Protocol Approved
		10. Name of Authorized Practitioner Signing the Prescription
		11. Name of the Patient Receiving the Prescription
		12. Serial Number of the Prescription
		11. Quantity Dispensed
		12. Balance Remaining after the Transaction
		13. Recorder's Initials
YES	NO	FOR EACH RESEARCH SUBJECT, THE PRINCIPAL INVESTIGATOR MAINTAINS THE FOLLOWING INFORMATION IN THE INVESTIGATIONAL DRUG/DEVICE LOG:
		1. Name of the Patient Receiving the Prescription
		2. Serial Number of the Prescription
		3. Quantity Dispensed
		4. Balance Remaining after the Transaction
YES	NO	DOES THE PRINCIPAL INVESTIGATOR ENSURE THAT INVESTIGATIONAL DRUGS OR DEVICES ARE <u>NOT DISPENSED</u> WITHOUT THE FOLLOWING SCANNED INTO THE PATIENT'S ELECTRONIC MEDICAL RECORD:
		1. Signed Informed Consent Form
		2. VA Form 10-9012 (Investigational Drug Information Record)
YES	NO	IS THE PRINCIPAL INVESTIGATOR COMPLYING WITH THE POLICIES AND PROCEDURES REGARDING THE USE OF INVESTIGATIONAL DRUGS OR DEVICES IN THE FOLLOWING AREAS:
		1. Receipt
		2. Storage
		3. Security
		4. Dispensing
		5. Disposition

SIGNATURE OF RESEARCH PHARMACIST

DATE

SIGNATURE OF PRINCIPAL INVESTIGATOR

DATE