INVESTIGATIONAL AGENT AUDIT CHECKLIST

Drug name(s): _____

Protocol #_____ Protocol Version _____

Audit Interval _____

Study coordinator/data manager: _____

Lead Pharmacist (if applicable): _____

Date of Last Audit (if applicable): _____

Accountability records:

___ Electronic records

___ Paper records

___ Mixed records (paper and electronic)

NOTE! This checklist is intended to be used for preparation of the site for audit and should not be shared with the auditor(s).

Step 1: Preparation of file and site (place a √ or indicate NA)

_____ Gather the investigational agent/drug file, Investigational Product (IP) logs, prescriptions, notebook (if used) and other records (including satellite records if applicable) to present to auditor since last audit (if applicable).

_____ If study is closed, obtain closed file.

_____ Sort drug receipts in chronological order.

_____ Sort return/destruction forms in chronological order.

_____ Sort transfer forms in chronological order.

_____ Sort Central and Satellite accountability records by location and date.

_____ Sort all other records by date (e.g., randomization information, worksheets).

_____ Organize prescriptions and paper orders (if applicable) by patient last name in alphabetical order or by subject number from smallest to largest then in chronological order.

_____ For audits that review selected patients, obtain the list of patients to be audited from the auditor or study coordinator/data manager for the study.

_____ Reserve conference room for auditors if audit is occurring on-site.

_____ For remote audits, ensure that all necessary files are scanned. These files must match the original source and/or uploaded in accordance with site regulatory SOP with consistent file nomenclature.

Step 2: Preparation of central and satellite investigational agent records.

	Y	N	N/A	Comments
Drug Acquisition				
Drug receipts are signed and dated. Shipping records maintained in the study binder/file.				
Lot number and expiration date are recorded on receipts. If expiration date is not available, “unknown” is inserted. Lot number should not be "unknown".				

	Y	N	N/A	Comments
Manufacturer and supplier for all IP receipts is recorded on the Drug Accountability Record Form (DARF).				
Confirm temperature device data downloaded and report printed for all receipts, if applicable.				
Drug arrival confirmed with sponsor, if applicable (with receipt of confirmation).				
Drug Accountability Record Form (DARF)-Compliance with Protocol Requirements				
For National Cancer Institute (NCI)-supplied agents, NCI DARF is utilized. For non-NCI-supplied drugs, NCI DARF, sponsor DARF, or sponsor approved DARF is used. Check protocol/study documents and communication with sponsor to ensure that correct DARF/DARF version is used (the form did not expire).				
When NCI DARFs are used, ORAL NCI Investigational Agent DARF is used for all oral drugs.				
For NCI-supplied agents, if electronic DARFs are used instead of the NCI DARF, the eDARF printout is identical to the NCI DARF.				
For NCI-supplied agents, DARFs are not lot-specific (i.e., all lots are listed on same page).				
For NCI-supplied agents, for each shipment, the investigator listed on the shipping receipt is the same as the investigator listed on the DARF, and only one investigator is listed on each DARF.				
Patient-specific DARF is used, if required by protocol.				
Separate DARF is used for each study agent or placebo and each study protocol.				
Separate DARF is used for each study agent strength and dosage form, if applicable.				
If applicable, drug assignment (with appropriate documentation) for a blinded trial complies with the procedure described in the protocol/study documents.				
Drug Accountability Record Form (DARF)-Central Location				
Recordings on the DARF are maintained in a timely manner.				
DARF header/footer is properly and completely filled out (no blanks). (e.g., drug name, strength, lot number(s), expiration date if available, page number, etc.). Drug name matches IP receipt.				
If expiration date is not available, “unknown” is inserted.				
Drug dispensing unit and strength are recorded, if applicable.				
Balance forward is completed.				
Subject initials (not name) and subject study number (not medical record number) are recorded on DARF.				
Date and quantity of drug **receipt** are correctly recorded on DARF.				
Date and quantity drug **dispensed** are correctly recorded on DARF.				
Date, quantity and lot number of drug **transported to a satellite** are correctly recorded on DARF, if applicable.				
Date, quantity and lot number of unused drug **returned from a satellite** are correctly recorded on DARF, if applicable.				

	Y	N	N/A	Comments
Date and quantity of drug **destroyed/transferred to another study or another institution/returned** are correctly recorded on DARF and documentation is available for review, if needed.				
Only one dose dispensed is recorded for individual subjects on each line entry.				
Number of units used for compounded preparations is appropriate for the dose.				
The inventory balance for each line on the DARF is correct (i.e., math).				
Corrections made with single line strike through, dated and initialed (no erasures and whiteouts) with black or blue ink. No ditto marks.				
All entries are initialed and dated.				
All entries are dated in chronological order. If date is not in sequential order, there is a note to file or comments with an explanation.				
Actual drug inventory matches drug accountability record.				
Drug Accountability Record Form (DARF)-Satellite Location (Fill if a satellite is used. Duplicate this section if more than one satellite is used).				
Recordings on the DARF are maintained in a timely manner.				
DARF header/footer is properly and completely filled out (no blanks). (e.g., drug name, strength, lot number(s), expiration date if available, page numbers, etc.). Drug name matches IP receipt.				
If expiration date is not available, “unknown” is inserted.				
Drug dispensing unit and strength are recorded, if applicable.				
Balance forward is completed.				
Subject initials (not name) and subject study number (not medical record number) are recorded on DARF				
Date, quantity and lot number of drug **received** from central location are correctly recorded on DARF.				
Date, quantity and lot number of unused drug **returned to a central location from a satellite** are correctly recorded on DARF.				
Date and quantity of drug **dispensed** are correctly recorded on DARF.				
Only one dose dispensed is recorded for individual subjects on each line entry.				
Number of units used for compounded preparations is appropriate for the dose.				
The inventory balance for each line on log is correct (i.e., math).				
Corrections made with single line strike through, dated and initialed (no erasures and whiteouts). No ditto marks.				
All entries are initialed and dated.				
All entries are dated in chronological order. If date is not in sequential order, there is a note to file or comments with an explanation.				
Actual drug inventory matches drug accountability record.				
Drug Transfers/Transports				

	Y	N	N/A	Comments
If drug is **transferred** to another protocol, transfer must be approved by CTEP or study sponsor in advance, documentation must be available. For NCI-supplied agent, NCI Transfer Investigational Agent Form must be used.				
If drug **transferred** to another site, transfer must be approved by CTEP or study sponsor in advance, documentation available.				
If NCI-supplied agent was transported or transferred to other investigators or locations, it was not repackaged or reshipped by mail or express carrier.				
Drug Return / Destruction				
Returned drug from subjects documented on the same DARF that lists the dispensing.				
Returned drug from subjects is available for review if specified by the sponsor. If used drug was returned to sponsor/destroyed on site, documentation is available.				
For NCI-supplied agents, expired drug is returned/destroyed within 90 calendar days of expiration. Drug return/destruction document available.				
For NCI-supplied agents, if the study is closed, unused/un-dispensed drug is returned/destroyed per protocol 90 calendar days after the close date.				
For NCI-supplied agents, documentation of NCI approval of the destruction on site and all communication with the NCI is available.				
If drug is destroyed, there is a local site destruction policy available.				
Storage and Security				
Drugs are physically stored separately by protocol in container labeled with drug name and protocol number. Drugs are separated by strength and dosage form. For NCI-supplied drug the agents need to be stored by ordering or designated ordering investigator.				
Drugs are stored under proper conditions (refrigeration, freezer and room temperature).				
Temperatures at the storage area are documented and monitored.				
If there was a temperature excursion, there is documentation of correspondence that the study sponsor was contacted, if applicable.				
If there was a temperature excursion, the drug was quarantined, if applicable.				
Drug stored in secured and limited access area.				
Prescriptions				
Prescriptions/orders are signed by authorized prescribers. For NCI-supplied agents, the investigator prescribing or co-signing must have an active registration status as either Prescribing Investigator (IVR) or Nonphysician Investigator (NPIVR) in the CTEP Registration and Credential Repository (RCR).				
Patient Specific Reviews				
The correct study agent (correct protocol number, correct study supply) was dispensed to the patient.				

	Y	N	N/A	Comments
Only study supplied drug is dispensed and recorded on DARF. Commercial drug is not substituted for study provided drug. Study agents cannot be borrowed.				
For oral drugs or drugs dispensed for home administration doses and start/end dates listed on the Case Report Form (or equivalent) match the drug accountability records.				
For drugs administered in the clinic, doses and dates provided on the Case Report Form (or equivalent) match the drug accountability records.				
Study drug is only dispensed to subjects who are registered to the study.				

General Suggestions:

- If applicable, un-blinding performed by pharmacy or other study personnel is documented.
- Patient list (Master Log) is available and up-to-date, especially for sites using paper records. Same patient initials and study number used on master log and dispensing record.
- Investigational agent handling and dispensing instructions available.
- All materials organized neatly and easily accessible.
- Most current version of the protocol that is approved by IRB is available and has been reviewed.
- Most current version of site SOPs (e.g. destruction, returns, transfer/transport) are available.
- Ensure that pharmacy training logs are complete and up to date with the most recent IRB-approved protocol.

Additional Comments:

Prepared by: _____/_____
Name Date

Reviewed by (pharmacist/study staff): _____/_____
Name Date

Resources:

- NCI audit guidelines for auditing clinical trials (revised April 2023) https://ctep.cancer.gov/branches/ctmb/clinicalTrials/docs/NCTN_Auditing_Guidelines.pdf#search=%22audit%20guidelines%22 (Last accessed 23Dec2024)
- NCI Pharmacy Audit Worksheet http://ctep.cancer.gov/branches/ctmb/clinicalTrials/docs/Pharmacy_Audit_Worksheet.pdf (Last accessed 23Dec2024)
- SWOG Quality Assurance Audit Guidelines https://www.swog.org/sites/default/files/docs/2023-12/QA%20Guidelines_12.15.23.pdf (Last accessed 23Dec2024)

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