INVESTIGATIONAL AGENT AUDIT CHECKLIST

Drug name(s): _____

Protocol #_____ **Protocol Version** _____

Audit Date _____

Study coordinator/data manager: _____

Lead Pharmacist (if applicable): _____

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 (place a √ or indicate NA)

_____ Gather the investigational agent/drug file, notebook and records (including satellite records if applicable).
_____ If study is closed, obtain closed file.
_____ Sort drug receipt invoices by date.
_____ Sort return/destruction forms by date.
_____ Sort transfer forms by date.
_____ Sort Central and Satellite accountability records by location and date.
_____ Sort all other records by date (e.g., randomization information, worksheets).
_____ Organize prescriptions by patient in chronological and alphabetic 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.

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

	Y	N	N/A	Comments
Drug Acquisition				
Invoices signed and dated. Shipping records maintained in the study binder.				
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). Check protocol/study documents and communication with sponsor regarding instruction on using lot-specific logs.				
For NCI-supplied agents, for each shipment, the investigator that is listed on the shipping receipt is 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 and each study protocol.				

	Y	N	N/A	Comments
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. (e.g., drug name, strength, lot number(s), expiration date if available, page number, etc.).				
If expiration date is not available, "NA" is inserted.				
Drug dispensing unit and strength is recorded, if applicable.				
Balance forward is completed.				
Subject initials (not name) and subject study number (not medical record number) recorded on DARF				
Date and quantity of drug **receipt** is correctly recorded on DARF.				
Date and quantity drug **dispensed** is correctly recorded on DARF.				
Date, quantity and lot number of drug **transported to a satellite** is correctly recorded on DARF.				
Date, quantity and lot number of unused drug **returned from a satellite** is correctly recorded on DARF.				
Date and quantity of drug **destroyed/transferred to another study or another institution/returned** is 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). 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. (e.g., drug name, strength, lot number(s), expiration date if available, page numbers, etc.).				
If expiration date is not available, NA is inserted.				
Drug dispensing unit and strength is recorded, if applicable.				
Balance forward is completed.				
Subject initials (not name) and subject study number (not medical record number) recorded on DARF				
Date, quantity and lot number of drug **received** from central location is correctly recorded on DARF.				

	Y	N	N/A	Comments
Date, quantity and lot number of unused drug **returned to a central location from a satellite** is correctly recorded on DARF.				
Date and quantity of drug **dispensed** is 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 (ie, 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				
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, patients or locations, it was <u>not</u> 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 days of expiration. Drug return/destruction document available.				
For NCI-supplied agents, if the study is closed, drug is returned/destroyed per protocol 90 days after the close date.				
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				

	Y	N	N/A	Comments
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/Orders				
Prescriptions/orders are signed by authorized prescribers. For NCI-supplied agents, investigator prescribing or cosigning must have an active investigator registration with CTEP.				
Patient Specific Reviews				
The correct study agent (correct protocol number, correct study supply) was dispensed to the patient.				
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 not dispensed to subjects that are not registered to 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. 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. Protocol binder includes tabs to separate sections.
- Most current version of the protocol that is approved by IRB is available and has been reviewed.

Additional Comments:

Prepared by: _____/_____
Name **Date**

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

Resources:

- NCI audit guidelines for auditing clinical trials (revised February 2014) http://ctep.cancer.gov/branches/ctmb/clinicalTrials/docs/ctmb_audit_guidelines.pdf (Last accessed 19Nov2014)
- NCI Pharmacy Audit Worksheet http://ctep.cancer.gov/branches/ctmb/clinicalTrials/docs/Pharmacy_Audit_Worksheet.pdf (Last accessed 19Nov2014)
- SWOG Quality Assurance Audit Guidelines https://swog.org/Members/Download/QA/QA%20Guidelines_9.11.pdf (Last accessed 19Nov2014)

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