Clinical Trials Monitoring Branch (CTMB)
Cancer Therapy Evaluation Program (CTEP)
Division of Cancer Treatment and Diagnosis (DCTD)

Pharmacy Review Worksheet

Audit Date:_____ **CTEP Site Code:** _____ **On-site or Off-site (circle one)**

Were study-supplied agents in-use at this site during the time period covered by this audit? Y or N

# of NCI DARFs compared to shelf inventory: _____

# of patients cross-checked with NCI: _____

List protocols (DARFs) reviewed: _____

_____

	* Critical Non-Compliant	Non-Compliant	Compliant	Not Reviewed	Overall Comments
NCI DARFs Completely and Correctly Filled Out	[ ]	[ ]	[ ]	[ ]	
DARFs Protocol and Study Agent Specific	[ ]	[ ]	[ ]	[ ]	
Satellite Records of Dispensing Area	[ ]	[ ]	[ ]	[ ]	
NCI DARFs Kept as Primary Transaction Record	[ ]	[ ]	[ ]	[ ]	
Return of Study Agent [NCI-sponsored study]	[ ]	[ ]	[ ]	[ ]	
Study Agent Storage	[ ]	[ ]	[ ]	[ ]	
Adequate Security	[ ]	[ ]	[ ]	[ ]	
Authorized Prescription(s)	[ ]	[ ]	[ ]	[ ]	

***** Any finding identified before or during an audit that is suspected to be fraudulent activity.

Pharmacy Review – List of Non-Compliance

Protocol #: _____

Study Agent Name: _____

NCI DARFs Completely and Correctly Filled Out	Non-Compliance		
	[✓] if Critical	Yes	No
NCI DARF not maintained or not maintained completely, accurately or on a timely basis	[ ]	[ ]	[ ]
Oral NCI DARF not maintained for oral study-supplied agents, not maintained completely, accurately or on a timely basis	[ ]	[ ]	[ ]
Lack of a DARF(s) to verify cancer control/imaging study supplied agents are administered to patients/study participants	[ ]	[ ]	[ ]
Paper and/or electronic DARFs (eDARFs) do not contain all information or are not completed as required; paper printout of eDARF is not identical to the NCI DARF	[ ]	[ ]	[ ]
Erasures or "whiteouts" on paper DARF	[ ]	[ ]	[ ]
Corrections are not lined out, initialed and dated on paper DARF	[ ]	[ ]	[ ]
Corrections are not appropriately documented on eDARF in electronic inventory system	[ ]	[ ]	[ ]
Study-supplied agent dispensed to a registered patient/study participant and not recorded on the appropriate DARF	[ ]	[ ]	[ ]
Multiple dose vials not used for more than one patient/study participant and/or doses not documented correctly on separate lines of the DARF	[ ]	[ ]	[ ]
Dispensing of study-supplied agent to a non-registered patient/study participant recorded on the DARF	[ ]	[ ]	[ ]
Patient/study participant returns of oral study-supplied study agents *not* documented on the Oral DARF	[ ]	[ ]	[ ]
Patient/study participant returns of non-oral, non-patient-specific agent supplies are documented on the DARF	[ ]	[ ]	[ ]
Patient/study participant returns of non-oral, patient-specific agent supplies are not documented on the DARF	[ ]	[ ]	[ ]
[For NCI-sponsored Study] NCI-supplied study agents are repackaged and/or reshipped to other investigators, patients, or locations by mail or express carrier	[ ]	[ ]	[ ]
[For NCI-sponsored Study] Study agent has been transferred to an unauthorized investigator or protocol without CTEP approval	[ ]	[ ]	[ ]

Pharmacy Review – List of Non-Compliance

Protocol #: _____

Study Agent Name: _____

DARFs Protocol and Study Agent Specific	Non-Compliance		
	[✓] if Critical	Yes	No
Substitution of any study-supplied agent, with non-study supplied study agent, including commercial agents	[ ]	[ ]	[ ]
DARF maintained by lot #	[ ]	[ ]	[ ]
One DARF used for more than one protocol	[ ]	[ ]	[ ]
One DARF used for a protocol using multiple study agents	[ ]	[ ]	[ ]
One DARF used for multiple agent strengths, dosage forms, or ordering investigators	[ ]	[ ]	[ ]
Single DARF used for multiple patients/study participants on study when patient-specific DARF should be maintained	[ ]	[ ]	[ ]
Study-supplied agent used for pre-clinical or laboratory studies without written approval by NCI	[ ]	[ ]	[ ]

Satellite Records of Dispensing Area	Non-Compliance		
	[✓] if Critical	Yes	No
No satellite DARFs in use when required	[ ]	[ ]	[ ]
Satellite DARFs not available at the time of the audit	[ ]	[ ]	[ ]
Satellite and Control records do not match or are not accurately maintained	[ ]	[ ]	[ ]
Unused and un-dispensed study-supplied agent is not documented as returned to Control dispensing area; Satellite Dispensing Area is inappropriately transferring and/or locally destroying study-supplied agent	[ ]	[ ]	[ ]

Pharmacy Review – List of Non-Compliance

Protocol #: _____

Study Agent Name: _____

NCI DARFs Kept as Primary Transaction Record	Non-Compliance		
	[✓] if Critical	Yes	No
Study-supplied agent order receipts/documentation are not retained or not available for review	[ ]	[ ]	[ ]
Lack of documentation on Control DARF of study-supplied agent transactions and local destruction	[ ]	[ ]	[ ]
Quantities not accounted for in physical inventory; quantity does not match DARF	[ ]	[ ]	[ ]
[For NCI-sponsored Study] No written documentation of NCI authorization of transfer or local destruction of NCI-supplied study agent maintained	[ ]	[ ]	[ ]

Return of Study Agent [NCI-sponsored studies]	Non-Compliance		
	[✓] if Critical	Yes	No
Unused/un-dispensed NCI-supplied study agent is not returned, not transferred to an appropriate NCI protocol or not destroyed within 90 days of notification from NCI; NCI-supplied study agent is locally destroyed without NCI authorization or not locally destroyed per local institution's destruction policy	[ ]	[ ]	[ ]
Agent returned to PMB that should have been destroyed on-site or agent returned to PMB that was not supplied by PMB	[ ]	[ ]	[ ]
Failure to maintain Return Form or documentation of authorized local destruction; no written NCI authorization for transfer or local destruction	[ ]	[ ]	[ ]
Unused/un-dispensed NCI-supplied study agents not returned, transferred or locally destroyed within 90 days when patients/study participants are in follow-up and no NCI-supplied study agent is being administered	[ ]	[ ]	[ ]
[For Non-NCI sponsored Study] Study agent final disposition of inventory is not documented on DARF	[ ]	[ ]	[ ]

Pharmacy Review – List of Non-Compliance

Protocol #: _____

Study Agent Name: _____

Study Agent Storage	Non-Compliance		
	[✓] if Critical	Yes	No
Study-supplied agent is not stored separately by protocol, strength, 'dosage form' (e.g., oral, injectable) and/or by ordering investigator	[ ]	[ ]	[ ]
Study-supplied agent not stored under proper temperature conditions; temperature monitoring documentation not maintained	[ ]	[ ]	[ ]

Adequate Security	Non-Compliance		
	[✓] if Critical	Yes	No
Study-supplied agent is stored in an unsecured area	[ ]	[ ]	[ ]
Unauthorized individuals have access to a secure	[ ]	[ ]	[ ]

Authorized Prescription(s)	Non-Compliance		
	[✓] if Critical	Yes	No
[For NCI sponsored Study] Investigator prescribing or co-signing an order for study supplied agent does not have an active investigator registration with CTEP or is not an authorized prescriber for the protocol	[ ]	[ ]	[ ]
[For NCI sponsored Study] An order for a study-supplied agent is not signed or co-signed by an authorized and registered investigator prior to study agent dispensing and administration	[ ]	[ ]	[ ]
Pharmacy does not have procedures in place to ensure person prescribing or cosigning prescriptions for study-supplied agent is an authorized prescriber	[ ]	[ ]	[ ]