PHARMACY AUDIT WORKSHEET

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

Pharmacy Review

CTEP Site Code: _____

Protocol Number: _____

Were INDs or NCI-supplied study agent used at this site during the period covered by this audit: **Y** or **N**	
Drug accountability checked during this audit: **Y** or **N**	
# of NCI DARFs (by study agent, dosage form, strength) compared to shelf inventory: _____	# of patients/study participants cross checked with NCI: _____

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

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NCI DARFs Completely and Correctly Filled Out (Non-Compliance)	Yes	No
NCI DARF not maintained or not maintained completely and accurately	[ ]	[ ]
Oral NCI DARF not maintained or not completely and accurately filled out	[ ]	[ ]
NCI DARF not maintained on a timely basis	[ ]	[ ]
Inability to track the receipt, use and disposition of NCI-supplied study agents	[ ]	[ ]
Incorrect agent, dose, or dates dispensed, incorrectly prepared drug, and/or incorrectly documented	[ ]	[ ]
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	[ ]	[ ]
NCI-supplied study agents are repackaged and/or reshipped to other investigators, patients, or locations by mail or express carrier	[ ]	[ ]
Agent has been transferred to an investigator who is not actively registered with CTEP	[ ]	[ ]
Dispensing of NCI-supplied study agent to a registered patient/study participant and not recorded or not recorded on the appropriate DARF	[ ]	[ ]

DARFs Protocol and Agent Specific (Non-Compliance)	Yes	No
Patient/study participant identified on DARF is not a registered patient/study participant	[ ]	[ ]
NCI-supplied study agent used for pre-clinical or laboratory studies without written approval by NCI	[ ]	[ ]
Substitution of any NCI-supplied study agent, with non-NCI supplied study agent, including commercial agents	[ ]	[ ]
Lack of a DARF(s) to verify NCI-supplied study agents are administered to patients/study participants or transported and delivered to investigators at Satellite Dispensing Areas and administered to patients/study participants	[ ]	[ ]
Each NCI-supplied study agent not accounted for separately by protocol	[ ]	[ ]
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 strengths, dosage forms of an agent, or multiple ordering investigators	[ ]	[ ]
Single DARF used for multiple patients/study participants on study when patient-specific DARF should be maintained	[ ]	[ ]
Multiple dose vials recorded for one patient/study participant instead of multiple patients/study participants, or multiple doses recorded on a single line of the DARF	[ ]	[ ]

Satellite Records of Dispensing Area (Non-Compliance)	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 study agent is not documented or returned to Control dispensing area; Satellite Dispensing Area is inappropriately transferring and/or locally destroying NCI-supplied study agent	[ ]	[ ]

NCI DARFs Kept as Primary Transaction Record (Non-Compliance)	Yes	No
NCI-supplied study agent order receipts (Shipment Record of Clinical Drug Request) not retained or not available for review	[ ]	[ ]
Lack of documentation on Control DARF of NCI-supplied study agent transactions and destruction	[ ]	[ ]
NCI-supplied study agents have been borrowed	[ ]	[ ]
Transfer Investigational Agent Form not used when transferring NCI-supplied study agent	[ ]	[ ]
No written documentation of NCI authorization of transfer or local destruction of NCI-supplied study agent maintained	[ ]	[ ]
Quantities not accounted for in physical inventory; quantity does not match DARF	[ ]	[ ]

Return of Study Agent (Non-Compliance)	Yes	No
NCI-supplied study agent is not returned, not transferred to an appropriate NCI protocol or not destroyed within 90 days; NCI-supplied study agent is destroyed without NCI authorization or not destroyed per local institution's destruction policy	[ ]	[ ]
Failure to maintain Return Form or documentation of local destruction; no written NCI authorization for transfer or for local destruction	[ ]	[ ]
NCI-supplied study agents not returned, transferred or destroyed when patients are in follow-up and no NCI-supplied study agent is being administered	[ ]	[ ]
Patient returns of NCI-supplied study agents are not recorded on the patient-specific DARF for patient-specific supply studies	[ ]	[ ]
Patient returns of oral NCI-supplied study agents *not* documented appropriately on the Oral DARF	[ ]	[ ]
Patient returns of non-oral, non-patient-specific supplies *are* recorded on the DARF	[ ]	[ ]

Study Agent Storage (Non-Compliance)	Yes	No
NCI-supplied study agents not stored separately by protocol, different strength or 'dosage form' (eg, oral, injectable) and by ordering or designated ordering investigator (by Group)	[ ]	[ ]
NCI-supplied study agents used for more than one protocol combined in storage	[ ]	[ ]
NCI-supplied study agent not stored under proper conditions; temperature monitoring documentation not maintained	[ ]	[ ]

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Adequate Security (Non-Compliance)	Yes	No
NCI-supplied study agent is stored in an insecure area	[ ]	[ ]
Unauthorized individuals have access to a secure area without supervision	[ ]	[ ]

Unauthorized Prescription(s) (Non-Compliance)	Yes	No
NCI-supplied study agent is prescribed by a person not registered with CTEP as an investigator, or order was not co-signed by an active registered investigator	[ ]	[ ]
An order was not signed or co-signed by the registered investigator prior to study agent dispensing and administration	[ ]	[ ]
Pharmacy does not have procedures in place to ensure person prescribing or cosigning prescriptions for NCI-supplied study agent has an active investigator registration with CTEP	[ ]	[ ]