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

Pharmacy Review Worksheet

Review 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 review? 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 the review that meets the definition of a critical finding as defined in the CTMB auditing and monitoring guidelines.

Pharmacy Review – List of Non-Compliance

Protocol #: _____

Study Agent Name: _____

NCI DARFs Completely and Correctly Filled Out	[✓] if Non-Compliant		
	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	[ ]	[ ]	[ ]
DARF not maintained to verify cancer control/imaging study supplied agents are administered to patients/study participants	[ ]	[ ]	[ ]
Paper and/or electronic DARFs (eDARFs) are not completed as required; paper printout of eDARF is not identical to the NCI DARF	[ ]	[ ]	[ ]
Erasures or whiteout used 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 is 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 or locations by mail or express carrier	[ ]	[ ]	[ ]
Study agent final disposition of inventory is not documented on DARF	[ ]	[ ]	[ ]

Pharmacy Review – List of Non-Compliance

Protocol #: _____

Study Agent Name: _____

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

Satellite Records of Dispensing Area	[✓] if Non-Compliant		
	Critical	Yes	No
No satellite DARFs in use when required (i.e., stored more than a day)	[ ]	[ ]	[ ]
Satellite DARFs not available at the time of the review	[ ]	[ ]	[ ]
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	[✓] if Non-Compliant		
	Critical	Yes	No
Study-supplied agent order receipts/documentation (paper or electronic) are not retained or not available for review	[ ]	[ ]	[ ]
No documentation on Control DARF of study-supplied agent transactions and local destruction	[ ]	[ ]	[ ]
Quantities not accounted for in physical inventory; quantities do not match DARF	[ ]	[ ]	[ ]

Return of Study Agent [NCI-sponsored studies]	[✓] if Non-Compliant		
	Critical	Yes	No
Study agent is transferred to investigator or protocol without NCI written approval	[ ]	[ ]	[ ]
Study agent returned to PMB that should have been destroyed on-site or study agent returned to PMB that was not supplied by PMB	[ ]	[ ]	[ ]
Return Form or documentation of authorized local destruction not maintained	[ ]	[ ]	[ ]
Unused/un-dispensed NCI-supplied study agents not returned, transferred or locally destroyed within 90 calendar days when requested by the NCI, or when patients/study participants are in follow-up, study is closed to enrollment and no NCI-supplied study agent is being administered	[ ]	[ ]	[ ]

Pharmacy Review – List of Non-Compliance

Protocol #: _____

Study Agent Name: _____

Study Agent Storage	[✓] if Non-Compliant		
	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	[✓] if Non-Compliant		
	Critical	Yes	No
Study-supplied agent is stored in an unsecured area	[ ]	[ ]	[ ]
Unauthorized individuals have access to a secure area without supervision	[ ]	[ ]	[ ]

Authorized Prescription(s)	[✓] if Non-Compliant		
	Critical	Yes	No
[For NCI sponsored study] Prescribing investigator (IVR) or non-physician investigator (NPIVR) writing orders for study-supplied agent does not have an active registration status in the CTEP Registration and Credential Repository (RCR)	[ ]	[ ]	[ ]
[For NCI sponsored study] Prescribing investigator (IVR) or non-physician investigator (NPIVR) writing orders is not an authorized, study-eligible person, or is not qualified to write orders per institutional policy, their local, state laws and regulations, or follow applicable international requirements	[ ]	[ ]	[ ]
Pharmacy does not have procedures in place to ensure person prescribing and writing orders for study-supplied agent is an authorized person	[ ]	[ ]	[ ]