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

Patient Case Review Worksheet

Review Date:_____ **CTEP Site Code:** _____

Protocol #: _____ **Pt Case #:** _____

PATIENT CASE SUMMARY:

Category	Critical	Major	Lesser	NR*	OK	Overall Comments
Informed Consent	[ ]	[ ]	[ ]	[ ]	[ ]	
Eligibility	[ ]	[ ]	[ ]	[ ]	[ ]	
Treatment	[ ]	[ ]	[ ]	[ ]	[ ]	
Disease Outcome/ Response	[ ]	[ ]	[ ]	[ ]	[ ]	
Adverse Events	[ ]	[ ]	[ ]	[ ]	[ ]	
General Data Management Quality	[ ]	[ ]	[ ]	[ ]	[ ]	

* Not Reviewed

Patient Case Review – List of Deficiencies

Protocol Number: _____
Pt Case #: _____

Informed Consent			
Critical Defiency	**Yes**	**No**	**Comments**
Any finding identified before or during the review that meets the defintion of a critical finding as defined in the CTMB auditing and monitoring guidelines.	[ ]	[ ]	
Consent form document not signed and dated by the patient/study participant (or parent/legally authorized representative, if applicable)	[ ]	[ ]	
Patient/study participant signature cannot be corroborated	[ ]	[ ]	
Consent form not protocol specific	[ ]	[ ]	
Major Deficiencies	**Yes**	**No**	**Comments**
Failure to document the informed consent process with the study participant	[ ]	[ ]	
Patient/study participant signs consent form document containing changes not approved by the CIRB/IRB	[ ]	[ ]	
Consent form document missing	[ ]	[ ]	
Translated consent, short form or other form of translation not available or signed/dated by a non-English speaking patient/study participant	[ ]	[ ]	
Consent form not signed by patient prior to study registration/enrollment	[ ]	[ ]	
Consent form does not contain all required signatures	[ ]	[ ]	
Consent form used was not the most current IRB-approved version at the time of patient registration	[ ]	[ ]	
Consent form does not include updates or information required by IRB	[ ]	[ ]	
Re-consent not obtained as required	[ ]	[ ]	
Consent for ancillary/advanced imaging studies not executed properly	[ ]	[ ]	
Other (explain)	[ ]	[ ]	

Patient Case Review – List of Deficiencies (cont…)

Protocol Number: _____
Pt Case #: _____

Eligibility			
Critical Deficiency	**Yes**	**No**	**Comments**
Any finding identified before or during the review that meets the defintion of a critical finding as defined in the CTMB auditing and monitoring guidelines.	[ ]	[ ]	
Major Deficiencies	**Yes**	**No**	**Comments**
Review of documentation available confirms patient/study participant did not meet all eligibility criteria and/or eligibility requirements were not obtained within the timeframe as specified by the protocol	[ ]	[ ]	
Documentation missing; unable to confirm eligibility [Exception: Patients deemed ineligible based on laboratory/pathology reports following registration and changes based on central review of material.]	[ ]	[ ]	
Other (explain)	[ ]	[ ]	
Treatment *			
Critical Deficiency	**Yes**	**No**	**Comments**
Any finding identified before or during the review that meets the defintion of a critical finding as defined in the CTMB auditing and monitoring guidelines.	[ ]	[ ]	
Incorrect agent/treatment/intervention used	[ ]	[ ]	
Major Deficiencies	**Yes**	**No**	**Comments**
Additional agent/treatment/intervention used which is not permitted by protocol	[ ]	[ ]	
Dose deviations or incorrect calculations (error greater than +/- 10%)	[ ]	[ ]	
Dose modification/treatment interventions not per protocol; incorrectly calculated	[ ]	[ ]	

Patient Case Review – List of Deficiencies (cont…)

Protocol Number: _____
Pt Case #: _____

Treatment/intervention incorrect, not administered correctly, or not adequately documented	[ ]	[ ]	
Timing and sequencing of treatment/ intervention not per protocol	[ ]	[ ]	
Unjustified delays in treatment/intervention	[ ]	[ ]	
Other (explain)	[ ]	[ ]	

* NOTE (for NCTN only): Review of documentation for how and when treatment is administered should focus on the study/IND agents under investigation (i.e., start/stop times), unless otherwise specified in the protocol. Documentation of standard of care drug(s) should follow institutional policy.

Disease Outcome/Response

Critical Deficiency	**Yes**	**No**	**Comments**
Any finding identified before or during the review that meets the defintion of a critical finding as defined in the CTMB auditing and monitoring guidelines	[ ]	[ ]	
Major Deficiencies	**Yes**	**No**	**Comments**
Inaccurate documentation of initial sites of involvement	[ ]	[ ]	
Tumor measurements/evaluation of 'status of disease' not performed, not reported, or not documented per protocol	[ ]	[ ]	
Protocol-directed response criteria not followed	[ ]	[ ]	
Claimed response (ie, partial response, complete response, stable) cannot be verified, or auditor/monitor could not verify the reported response	[ ]	[ ]	
Failure to detect cancer (as in a prevention study) or failure to identify cancer progression	[ ]	[ ]	
Other (explain)	[ ]	[ ]	

Patient Case Review – List of Deficiencies (cont…)

Protocol Number: _____
Pt Case #: _____

Adverse Events			
Critical Deficiency	**Yes**	**No**	**Comments**
Any finding identified before or during the review that meets the defintion of a critical finding as defined in the CTMB auditing and monitoring guidelines	[ ]	[ ]	
Major Deficiencies	**Yes**	**No**	**Comments**
Failure to report or delayed reporting of an adverse event that would require filing an expedited Adverse Event (AE) report or reporting to the Group	[ ]	[ ]	
Adverse events not assessed by the investigator in a timely manner (per protocol)	[ ]	[ ]	
Grades, types, or dates/duration of serious adverse events inaccurately recorded	[ ]	[ ]	
Adverse events cannot be substantiated	[ ]	[ ]	
Follow-up studies necessary to assess adverse events not performed	[ ]	[ ]	
Recurrent under- or over-reporting of adverse events	[ ]	[ ]	
Other (explain)	[ ]	[ ]	
General Data Management Quality			
Critical Deficiency	**Yes**	**No**	**Comments**
Any finding identified before or during the review that meets the defintion of a critical finding as defined in the CTMB auditing and monitoring guidelines	[ ]	[ ]	
Major Deficiencies	**Yes**	**No**	**Comments**
Recurrent missing documentation in the patient/study participant records	[ ]	[ ]	
Protocol-specified laboratory tests or other parameters not done, not reported or not documented	[ ]	[ ]	

Patient Case Review – List of Deficiencies (cont…)

Protocol Number: _____
Pt Case #: _____

Protocol-specified diagnostic studies including baseline assessments not done, not reported or not documented	[ ]	[ ]	
Protocol-specified research (Quality of Life forms, collection of research samples, etc.)/ advanced imaging studies not done or submitted appropriately	[ ]	[ ]	
Frequent data inaccuracies	[ ]	[ ]	
Errors in submitted data; data cannot be verified	[ ]	[ ]	
Delinquent data submission*	[ ]	[ ]	
Other (explain)	[ ]	[ ]	

* NOTE: See CTMB NCTN Auditing or ETCTN Monitoring Guidelines for measures to follow when assigning a major or lesser deficiency.