



Patient Case Audit Worksheet

Audit 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 Deficiency	Yes	No	Comments
Any finding identified before or during an audit that is suspected to be fraudulent activity	[]	[]	
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 an audit that is suspected to be fraudulent activity	[]	[]	
Major Deficiencies	Yes	No	Comments
Review of documentation available at the time of the audit 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 an audit that is suspected to be fraudulent activity	[]	[]	
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)	[]	[]	
Disease Outcome/Response			
Critical Deficiency	Yes	No	Comments
Any finding identified before or during an audit that is suspected to be fraudulent activity	[]	[]	
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 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 an audit that is suspected to be fraudulent activity	[]	[]	
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 an audit that is suspected to be fraudulent activity	[]	[]	
Major Deficiencies	Yes	No	Comments
Recurrent missing documentation in the patient/study participant records	[]	[]	
Protocol-specified laboratory tests or other parameters (Quality of Life forms, collection of research samples, etc.) not done, not reported or not documented	[]	[]	
Protocol-specified diagnostic studies including baseline assessments not done, not reported or not documented	[]	[]	
Protocol-specified research/advanced imaging studies not done or submitted appropriately	[]	[]	

Patient Case Review – List of Deficiencies (cont...)

Protocol Number: _____

Pt Case #: _____

Frequent data inaccuracies	[]	[]	
Errors in submitted data; data cannot be verified	[]	[]	
Delinquent data submission (> 6 months delinquent is considered a major deficiency; a 3-6 month delinquency is considered a lesser deficiency)	[]	[]	
Other (explain)	[]	[]	