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**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; un-redacted dataa | [ ] | [ ] |  |
| Errors in submitted data; data cannot be verified | [ ] | [ ] |  |
| Delinquent data submissionb | [ ] | [ ] |  |
| Other (explain) | [ ] | [ ] |  |

aAssigning a major or lesser deficiency is dependent on the number of instances and type of un-redacted data (e.g., security number, patient name, etc.).

b Assigning a major or lesser deficiency is based on the following: extent of the delay, percentage or number of delinquent forms, type of form (baseline, treatment, follow-up, etc), phase of the trial, patient on active treatment versus follow-up, etc. Due diligence on the part of the Group/NCORP policies and decisions from Data Quality Working Group should be taken into consideration.