|  |
| --- |
| GENERAL PROTOCOL INFORMATION |
| Report Date:       | Protocol No.       | IRB No.       |
| **Protocol Title:**       | **Phase:**      **Risk/Complexity:**       |
| **Principal Investigator:**       | **Original IRB Approval Date:**       |
| Report Frequency *(select initial if first review):* [ ] Initial [ ] Annual [ ] Semi-Annual [ ] Quarterly [ ] Other |

Sections Highlighted in Green – DSMC Committee Reviewer Only

|  |
| --- |
| 1. ENROLLMENT STATUS
 |
| * 1. Please indicate where each patient is in this trial by filling out the table below *(please add notes when necessary for clarification)*:

|  |
| --- |
| Target Accrual: |
|  |
| Last Review: |
| Totals Since Study Opened |
| \*\*TOTAL ACCRUAL |  |
|  Total consented (Main) |  |
|  Total consent not treat |  |
|  Total eligible to go on treatment/study |  |
|  Total screen fail or ineligible (pt unable to be put on study after consent) |  |
| \*\*CURRENT: Total on treatment/study |  |
| \*\*CURRENT: Total on follow-up |  |
|  Total completed active treatment/study procedures – now on follow-up (if study has specified number of tx/procedures) |  |
|  Total discontinued early – now on follow-up (ex. PD, Death, Toxicity) |  |
| \*\*OFF STUDY: total PD, death, toxicity – unable to complete study or follow-up |  |
| \*\*OFF STUDY: total completed all tx/ procedures and all follow-up |  |
| \*\* Highlighted columns should add up to TOTAL ACCRUAL |  |  |
| New/Changes in pt status/movement (on/off) since last DSMC review/report |
| New consents (Procurement) |  |
| New consent (Main Treatment) |  |
| New or determined eligible since last report |  |
| New screen fail/ineligible since last report |  |
| New on treatment/study procedures |  |
| New placed on follow-up |  |
| New discontinued |  |
| New off study |  |

1. If more than 2 new patients have been consented not treated SINCE LAST REPORT, provide explanation for each:
2. Patients that did not complete treatment SINCE LAST REPORT, list treatment non-completion reason for each:
 |
| 1. STOPPING RULES
 |
| * 1. Are there stopping rules for toxicity in this study? [ ] Y [ ] N [ ] N/A

If YES – attach/submit copy of stopping rules for toxicity with report |
| * 1. Are there stopping rules for response in this study? [ ] Y [ ] N [ ] N/A

If YES – attach/submit copy of stopping rules for response with report |
| * 1. If YES to question 2.1 or 2.2 please include:
		1. Meeting minutes discussing number of toxicities in relation to stopping rules. (Please notate within the minutes)

Meeting minutes attached: [ ] Y  |
| 1. TOXICITIES: AEs, ≥ GR 3 AEs, SAEs and PRIs
 |
| * 1. Report of all AEs, SAEs, PRIs since study inception:
		1. CTO-studies: OnCore generated AE reports and copies of SAE/PRI reports.
		2. Non-CTO studies: AE list/report, and copies of SAE/PRI reports. All AE/SAE/PRI events MUST include date of event, grade/s, and attribution.

Attachment: [ ] Y [ ] None to report [ ] N/APlease check box below if any of the following are included in the attached reports: SAE [ ]  DLT [ ]  Hospitalization [ ]  * 1. Please attach report of all GR 3 or greater AEs to-date:
		1. CPO-studies: OnCore generated AE reports.
		2. Non-CPO studies: List/report of AEs

Attachment: [ ] Y [ ] None to report [ ] N/A Please check box below if any of the following are included in the attached reports: SAE [ ]  DLT [ ]  Hospitalization [ ] * 1. Please attach all SAEs since last DSMC report (or study start if first review).
		1. Please attach FULL SAE/MedWatch report (including attribution):

Attachment: [ ] Y [ ] None to report *If N/A to any of the above items, please provide explanation here*:  |
| REVIEWER COMMENTS: |
|  |
| 1. DEVIATIONS/VIOLATIONS, UNANTICIPATED PROBLEMS (UPs)
 |
| * 1. Attach UPs that required immediate reporting since last review (or study start if first review).
		1. Please attach full UP report submitted to the IRB:

Attachment: [ ] Y [ ] None to report [ ] N/A If yes, is IRB Report attached? [ ] * 1. Attach ALL deviations/violations since last review (or study start if first review).

Attachment: [ ] Y [ ] None to report [ ] N/A (Please provide report in chronological order by “Report Date”)Are there new deviations to report since last review? [ ] *If N/A to any of the above items, please provide explanation here*:   |
| REVIEWER COMMENTS: |
|  |
| 1. HIGH RISK PH I OR PH I/II TRIALS ONLY
 |
| * 1. Phase I or I/II with dose escalation: What dose finding design is used in the trial? \_\_\_\_\_\_\_\_\_\_ Indicate adherence to dose escalation scheme in table below. If using 3+3 design, please show data by cohorts of three rather than cumulative: [ ] N/A

|  |  |  |
| --- | --- | --- |
| Dose Level(s) (List below – please specify dosing at each level) | # of Pts in Dose Level  | # of DLT in Any Pta |
| Pts since study start | Since Last DSMC Report | Since study start | Since Last DSMC Report |
|       |       |       |       |       |
|       |       |       |       |       |
|       |       |       |       |       |
|       |       |       |       |       |
| Totals (Should equal sum of prior rows) |       |       |       |       |

1. For any patient that had a Dose Limiting Toxicity (DLT), please list each by type and cohort:
 |
| * 1. Phase I/II Only:
		1. Describe transition to Phase II: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
		2. Attach preliminary report of response and other endpoints listed in primary and secondary objectives

Attachment: [ ] Y [ ] None [ ] N/A |
| 1. ELIGIBILITY/TREATMENT EXCEPTION(S)
 |
| * 1. List eligibility or tx exceptions since last review (or study start if first review):

[ ] Y [ ] None [ ] N/A |
| 1. MONITOR/AUDIT REPORT(S)
 |
| * 1. If study monitored and/or audited during review period – attach signed copy of report

Attachment: [ ] Y [ ] None during review period [ ] N/AProvide check all that apply:[ ]  CAPA (Describe Finding):[ ]  Action Items  Regulatory [ ]  Patient Data [ ]  Pharmacy [ ]  Eligibility and/or Consent [ ]  Other [ ]  Explain: |
| REVIEWER COMMENTS: |
|  |
| 1. LITERATURE: Developments that may affect safety or ethics of study
 |
| * 1. Attach copy of significant literature:

Attachment: [ ] Y [ ] None during review period [ ] N/A |
| 1. TEAM MEETING MINUTES
 |
| * 1. Attach copies of team meeting minutes since last review *Please highlight study specific discussion within team minutes:*

Attachment: [ ] Y [ ] None [ ] N/A |
| 1. INTERIM ANALYSES
 |
| * 1. Attach results of interim analyses (if applicable):

Attachment: [ ] Y [ ] None [ ] N/A  |
| 1. PROTOCOL
 |
| * 1. Attach most recent approved version of protocol - [ ] No change

[ ]  New Amendment Updates or changes include: Scientific [ ]  Editorial [ ]  Eligibility [ ]  |
| REVIEWER COMMENTS: |
|  |

|  |
| --- |
| CONTACT INFORMATION |
| Name of person submitting form: Email:Phone number:  |

|  |
| --- |
| **REVIEWER COMMENTS & RECOMMENDATION:** |
|  |

Sections Highlighted in Green – DSMC Committee Reviewer Only