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| GENERAL PROTOCOL INFORMATION | | |
| Report Date: | Protocol No. | IRB No. |
| **Protocol Title:** | | **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

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| 1. ENROLLMENT STATUS |
| |  |  |  |  | | --- | --- | --- | --- | | Please indicate where each patient is in this trial by filling out the table below: | | | | | Target Accrual for Study: | | | | | Last Review: | | \*\*TOTAL ACCRUAL | |  | | | Total consented | |  | | | Total eligible to go on study | |  | | | Total ineligible (pt unable to be put on study after consent) | |  | | | \*\*CURRENT: Total on intervention (if applicable) or on study | |  | | | \*\*CURRENT: Total on follow-up (This only applies to protocols that have a defined follow-up period) | |  | | | Total completed active intervention (if applicable) or active study procedures – now on follow-up. | |  | | | Total discontinued active intervention/study procedures early – now on follow-up (eg Progressive Disease, AE or Investigator Decision) | |  | | | \*\*OFF STUDY: total - unable to complete study procedures or follow-up period | |  | | | \*\*OFF STUDY: total completed active intervention/study 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 | |  | | | New or determined eligible since last report | |  | | | New ineligible since last report | |  | | | New on study | |  | | | New placed on follow-up (if study has defined follow-up period) | |  | | | New discontinued early (eg withdrawal, death) | |  | | | New off study | |  | |  1. If more than 2 new patients have been consented not progressed on to active study procedures SINCE LAST REPORT, provide explanation for each: 2. Patients that did not complete all study procedures SINCE LAST REPORT, list non-completion reason for each: |
| 1. TOXICITIES: 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/A  If N/A provide Explanation: |
| REVIEWER COMMENTS: | |
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| 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 N/A provide Explanation:   * 1. Attach ALL protocol deviations/violations since last review (or study start if first review)   Attachment: Y None to report N/A  If N/A provide explanation: |
| REVIEWER COMMENTS: | |
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| 1. ELIGIBILITY EXCEPTION(S) |
| * 1. List eligibility exceptions since last review (or study start if first review): |
| 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:   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.   Attachment: Y No change |
| REVIEWER COMMENTS: | |
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| CONTACT INFORMATION |
| Name of person submitting form:  Email:  Phone number: |

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| **REVIEWER COMMENTS & RECOMMENDATION:** |
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