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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
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| 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
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| * 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/AIf N/A provide Explanation:  |
| 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/AIf 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: |
|  |
| 1. ELIGIBILITY EXCEPTION(S)
 |
| * 1. List eligibility exceptions since last review (or study start if first review):
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| 1. LITERATURE: Developments that may affect safety or ethics of study
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| * 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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