**CLINICALTRIALS.GOV JHU RECORD REVIEW**

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|  **PROTOCOL ID** | **RECORD OWNER** | **REVIEWER** | **❑ Registration** **❑ Update status** **❑ Results** *(add Results checklist)* | **❑ pACT/ACT** **❑ Non-ACT**  |
| **NCT#** |
| **DATE RELEASED** | **COMMENTS DATE** | **REPLY DATE** | **DATE PUBLISHED** |
| **GENERAL REVIEW ITEMS** | **NOTES** |  |
| * If study has any grant funding, information provided should match what is on the grant application
* Record Owner is the PI or Coordinator (SKCCC) – Admin Only
* Contact info for Record Owner is up-to-date
* PI on record matches IRB PI: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* NCT# included in IRB “Clinical Trials Information” section
* All Warnings/Errors addressed
* All parenthetical citations have been removed
* All acronyms have been expanded on their first use
* Spell-check complete
* Free-text fields are blank if there is no information to report, and do not contain text such as “TBD,” “Pending,” “N/A,” “None”
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| **PROTOCOL SECTION** |  |
| **STUDY IDENTIFICATION*** Unique protocol ID is the IRB# or J# (SKCCC) (JHU Policy)
* Brief Title does not include study type (e.g., Phase I, Randomized…)
* Official title should match what is in the IRB (or grant application if applicable)
* Secondary IDs include NIH grant #s (verify in IRB), and IRB# (SKCCC)
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| **STUDY STATUS*** Record Verification Date is the current month/year
* Overall Status matches IRB/CRMS
* Study start date verified with CRMS enrollment date
* Completion Dates Actual/Anticipated have been evaluated for accuracy
* If timeframes for outcomes are the same the primary and study completion dates are identical
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| **SPONSOR/COLLABORATORS*** Responsible Party: Sponsor (JHU Policy)
* All sources of support identified in IRB “Support Information” section included as Collaborators
* Full Name used and if not recognized, “Recognize” is selected
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| **OVERSIGHT*** IND/IDE information completed (if applicable)
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| **Verify Human Subjects Review*** Board Status verified
* Approval Number is a valid IRB number
* Board Name: Johns Hopkins Medicine Institutional Review Board
* Board Affiliation: Johns Hopkins Medicine
* Phone: (410) 955-3008, Email: jhmeirb@jhmi.edu
* Address: 1620 McElderry Street, Reed Hall Suite B130, Baltimore, MD, 21205
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| **STUDY DESCRIPTION*** Brief Summary does not unnecessarily duplicate information provided for other data elements
* Brief Summary clearly states the study’s hypothesis or the purpose (for interventional and observational)
* Brief Summary and Detailed Description are written in complete sentences with no formatting errors
* Record does not use personal pronouns:“I, we, our, us, they, them, their” – becomes “the investigator(s)”; “you, your” – becomes “the participant(s)”
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| **CONDITIONS*** Conditions/Focus of study are discrete and does not use verbs or complete sentences
* Keywords are not numbered or bulleted, each condition and keyword is listed individually, one per line
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| **STUDY DESIGN*** All required fields are completed
* Verify Study Design based on protocol in IRB
* “Allocation” marked as “N/A” for single-arm interventional studies
* Enrollment number Actual/Anticipated verified
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| **ARMS/INTERVENTIONS*** Arm Title or Group/Cohort Label is brief and informative (even if there is only 1 arm)
* Interventions and intervention descriptions are entered correctly
* Arms/interventions are cross-referenced appropriately
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| **OUTCOME MEASURES*** Title is specific and states WHAT is being measured, only 1 variable must be assessed per outcome measure
* Description explains WHAT is being measured, not WHY it is being measured
* Scoring scale name, score range, significance of upper and lower limits specified (if applicable)
* Unit of measure specified
* Time frame specified as a single time point or change between 2 time points

INCORRECT: “Safety and Toxicity”, Description: “Safety of study drug.”CORRECT: *“Safety as assessed by number of participants experiencing adverse events”* Description: *“Number of participants experiencing adverse events grade 3 or higher, as defined by Common Terminology Criteria for Adverse Events version 5.0 (CTCAE v5.0)”* |
| **ELIGIBILITY*** Age Limits are consistent with the Eligibility Criteria and with other parts of the record
* Eligibility criteria is divided into Inclusion/Exclusion criteria in bulleted format
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| **CONTACTS/LOCATIONS*** Central Contact Person specified and accurate (JHU Policy)
* Study Officials match IRB
* All study sites specified matches CRMS
* Recruiting status for each study site accurate (if at least one study site is recruiting then Study Status reflects “Recruiting”)
* Each facility is listed in a separate field
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| **IPD Sharing Statement*** The Plan to Share IPD selection is consistent with the IPD Sharing Plan Description.
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| **REFERENCES*** Each citation is listed in a separate field (if applicable)
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***Add results checklist if results entry submitted.***

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| **RESULTS SECTION** |
| **PARTICIPANT FLOW*** Protocol Enrollment refers to total number of subjects who consented to protocol (including screen failures, withdrawals, etc.)
* Recruitment details (optional) explains any specifics used at time of recruitment
* Pre-assignment details explains (in detail) what happened to subjects who signed consent but were not assigned to an arm/intervention (i.e., how many screen failures, withdrawals, etc.)
* Arms and arm descriptions specified consistent with protocol section
* Number of Participants Started refers to total number of participants assigned to each arm
* Number of Participants Completed refers to total number of participants who completed study intervention
* Reason(s) for Not Completed provided
* Divided into periods/milestones appropriately
* Total number of participants started cannot be greater than enrollment number
* Total number completed is equal to or less than “started”
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| **BASELINE CHARACTERISTICS*** Overall Number of Baseline Participants should match Number of participants Started (from Participant Flow)
* Baseline Analysis Population Description explains if there is a discrepancy between Overall & Started numbers
* Arm titles/descriptions are consistent with participant flow and/or protocol section
* Data is presented per arm
* If “number of participants” is reported, make sure Measure Type is “Count of Participants”
* Measure description is specified for all Study-specific measures
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| **OUTCOME MEASURES*** Titles/descriptions/time frame meet the criteria (as specified on prior checklist)
* Results are reported per arm
* Analysis Population Description includes reason why Number of Participants analyzed is different than total number of participants completed (if applicable)
* Type and Number of Units analyzed is indicated, if other than “number of participants” (i.e., # of Lesions)
* Unit of measure matches what is stated in Outcome Title/Description
* Sum of all results entered for each arm equals overall number of participants analyzed
* Verify true data is entered and there are no placeholders
* Statistical Analysis portion is optional
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| **ADVERSE EVENTS*** Time frame specified
* Collection Approach specified
* Arm titles/descriptions consistent with other sections in the record
* Data presented per arm
* All-cause mortality specified (cross-check with number “not completed due to death” from participant flow and any mortality measures in outcome section, if applicable)
* Total Number “At Risk” must be equal to total number of participants who started the study
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| **CERTAIN AGREEMENTS*** Principal Investigators are employed by the organization sponsoring the study
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| **RESULTS POINT OF CONTACT*** Information is correct and valid email address/phone number entered
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| **DOCUMENT SECTION*** Protocol (required for primary completion date after January 18, 2017)
* Statistical Plan (required for primary completion date after January 18, 2017)
* Informed Consent Form (required for studies approved on or after January 21, 2019)
* Cover Page ❑ Record (NCT) Number ❑ Study Title❑ PI Name❑ Date of Document (must match date within actual document)
* Additional Documents: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
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| **REFERENCES*** Links are verified (if applicable)
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