**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” | | | |  | | |
| **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) | | | | | | |
| **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 | | | | | | |
| **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 | | | | | | |
| **OVERSIGHT**   * IND/IDE information completed (if applicable) | | | | | | |
| **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](mailto:jhmeirb@jhmi.edu) * Address: 1620 McElderry Street, Reed Hall Suite B130, Baltimore, MD, 21205 | | | | | | |
| **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)” | | | | | | |
| **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 | | | | | | |
| **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 | | | | | | |
| **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 | | | | | | |
| **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 | | | | | | |
| **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 | | | | | | |
| **IPD Sharing Statement**   * The Plan to Share IPD selection is consistent with the IPD Sharing Plan Description. | | | | | | |
| **REFERENCES**   * Each citation is listed in a separate field (if applicable) | | | | | | |

***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” |
| **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 |
| **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 |
| **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 |
| **CERTAIN AGREEMENTS**   * Principal Investigators are employed by the organization sponsoring the study |
| **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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **REFERENCES**   * Links are verified (if applicable) |