**CLINICALTRIALS.GOV RECORD REVIEW**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  **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** |  |
| * Record Owner is the PI or Coordinator (SKCCC)
* 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# (UI Policy)
* Brief Title does not include study type (e.g., Phase I, Randomized…)
* Secondary IDs include NIH grant #s (verify in IRB)
 |
| **STUDY STATUS*** Record Verification Date is the current month/year
* Overall Status matches IRB
* Study start date matches date on first signed consent document
* 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-investigator [unless instructed to complete differently] (UI Policy)
* All sources of support from other institutions/entities included as Collaborators (IRB sections III.1, VII.A.1)
* ‘University of Iowa’ is identified as an affiliate
 |
| **OVERSIGHT*** IND/IDE information completed (if applicable)
 |
| **Verify Human Subjects Review*** Board Status verified
* Approval Number is a valid IRB number
* Board Name: IRB 01 or University of Iowa IRB 01
* Board Affiliation: University of Iowa
* Phone: (319) 335-6564, Email: irb@uiowa.edu
* Address: 600 Newton Rd Suite 105, Iowa City, Iowa, 52246
 |
| **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 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 HOW outcome 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 pointsINCORRECT: “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 listed as a primary research team contact
* Study Officials match IRB
* All study sites specified matches IRB
* 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*** Field is completed with a ‘Yes’ or ‘No’ selection
* If ‘Yes’ is selected, an IPD Sharing Plan is identified
* 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.***

|  |
| --- |
| **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
* Population Analysis 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 completed
 |
| **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 NOT employed by sponsor as they are the sponsor
* Disclosure restrictions should be ‘No’ unless documentation is presented to the contrary
 |
| **RESULTS POINT OF CONTACT*** Information is correct and valid email address/phone number entered
 |

|  |
| --- |
| **DOCUMENT SECTION*** Documents in pdf/a format
* 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)
 |