CLINICALTRIALS.GOV NU 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
❑ If study has any grant funding, information provided should match what is on the grant application ❑ Record Owner is the PI or Coordinator – 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#
- ❑ 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#

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: Principal Investigator
- ❑ 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)

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
- ❑ 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.

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

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)