

CLINICALTRIALS.GOV UMB RECORD REVIEW

PROTOCOL ID (HP#)	RECORD OWNER	REVIEWER	<input type="checkbox"/> Registration <input type="checkbox"/> Update status <input type="checkbox"/> Results <i>(add Results checklist)</i>	<input type="checkbox"/> pACT/ACT <input type="checkbox"/> Non-ACT
NCT#				
DATE RELEASED	COMMENTS DATE	REPLY DATE	DATE PUBLISHED	
GENERAL REVIEW ITEMS			NOTES	
<ul style="list-style-type: none"> <input type="checkbox"/> No monetary value (e.g. compensation, food voucher) should be entered anywhere in the protocol <input type="checkbox"/> Record Owner is the PI <input type="checkbox"/> Contact info for Record Owner is up-to-date <input type="checkbox"/> PI on record matches IRB PI: _____ <input type="checkbox"/> NCT# included in IRB "Clinical Trials Information" section <input type="checkbox"/> All Warnings/Errors addressed <input type="checkbox"/> All parenthetical citations have been removed <input type="checkbox"/> All acronyms have been expanded on their first use <input type="checkbox"/> Spell-check complete <input type="checkbox"/> 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				
<ul style="list-style-type: none"> <input type="checkbox"/> Unique protocol ID is the IRB# (HP-000XXXXX) <input type="checkbox"/> Brief Title does not include study type (e.g., Phase I, Randomized...) <input type="checkbox"/> Official title should match what is in the IRB (or grant application if applicable) <input type="checkbox"/> Secondary IDs include NIH grant #s (verify in IRB), and IRB# (HP-000XXXXX) 				
STUDY STATUS				
<ul style="list-style-type: none"> <input type="checkbox"/> Record Verification Date is the current month/year <input type="checkbox"/> Overall Status matches IRB/CRMS <input type="checkbox"/> Study start date verified with CRMS enrollment date <input type="checkbox"/> Completion Dates Actual/Anticipated have been evaluated for accuracy <input type="checkbox"/> If timeframes for outcomes are the same the primary and study completion dates are identical 				
SPONSOR/COLLABORATORS				
<ul style="list-style-type: none"> <input type="checkbox"/> Responsible Party: PI <input type="checkbox"/> All sources of support identified in IRB "Support Information" section included as Collaborators <input type="checkbox"/> Full Name used and if not recognized, "Recognize" is selected 				
OVERSIGHT				
<ul style="list-style-type: none"> <input type="checkbox"/> IND/IDE information completed (if applicable) 				
Verify Human Subjects Review				
<ul style="list-style-type: none"> <input type="checkbox"/> Board Status verified <input type="checkbox"/> Approval Number is a valid IRB number <input type="checkbox"/> Board Name: University of Maryland, Baltimore Institutional Review Board <input type="checkbox"/> Board Affiliation: University of Maryland, Baltimore <input type="checkbox"/> Phone: (410) 706- 5037, Email: hrpo@umaryland.edu <input type="checkbox"/> Address: 620 W. Lexington St, 5th Floor, Baltimore, MD, 21202 				

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, my, we, our, us" – becomes "the investigator(s)"; "you, your, they, them, their" – 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 (drug or device names should be added to title and description)
- Arms/interventions are cross-referenced appropriately

OUTCOME MEASURES

- Title is "outcome neutral", specific and states WHAT is being measured, only 1 variable must be assessed per outcome measure (unless it is a composite)
- 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 (if unsure of duration, add up to the duration team is willing to follow each participant for that outcome measure e.g. "up to 1 year")
- Time points written in full e.g. 5 hours not 5hrs, 60 minutes not 60mins, 2 years not 2yrs
- Time frame is not the whole duration of study if outcome measure specifies a duration for the assessment of that measure which is less than whole duration of study

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: Martina Miller, UMB HRPO Analyst martina.miller@umaryland.edu
- Study Officials match CICERO
- All study sites specified match CICERO
- 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)

RESULTS SECTION

PARTICIPANT FLOW

- Protocol Enrollment refers to total number of subjects who consented to protocol (including 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 (optional)
- 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 or all participants together for crossover design
- 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 or by intervention for crossover design
- 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
- Time frame specified should not be more the duration of the study
- Statistical Analysis portion is optional (if entered, review for accuracy)

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

LIMITATIONS AND CAVEATS

- Information here should only be about limitations, unvalidated data or any reason why data entered cannot be totally reliable. It should not contain any discussion of results or any other information.

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: _____
- Uploaded document(s) does not include a publication

REFERENCES

- Links are verified (if applicable)