ClinicalTrials.gov Study Record Review

Investigator-Initiated Trial (IIT) Registration and Results Reporting

Quality Control Checklist
for Principal Investigators and Study Managers

Adapted with permission from the Clinical Trials Registration and Results Reporting Taskforce

Version 20180927

ClinicalTrials.gov IIT Record Review Checklist

IRB#	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 Principal Investigator (PI)
- ☐ Contact info for Record Owner is up-to-date
- ☐ PI on CT.gov record matches eIRB PI: _____
- ☐ NCT# included in eIRB and/or eCRIS
- ☐ 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…)
- ☐ 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: 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)

Verify Human Subjects Review

- ☐ Board Status verified
- ☐ Approval Number is a valid IRB number
- ☐ Board Name: OHSU Institutional Review Board
- ☐ Board Affiliation: Oregon Health and Science University
- ☐ Address: 2525 SW 1st Ave., Ste. 125, Mailcode L106-RI, Portland, OR 97201

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 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 -

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 of the trial
- ☐ 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 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

- ☐ 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)

Contact

Please contact the Clinical Research Services Office (CRSO)
for more ClinicalTrials.gov registration and results reporting information:

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