IRB EQUIP TIPS – CLINICALTRIALS.GOV CHECKLIST TO ADDRESS COMMON PRS ERRORS**

V 7.1 May 2025

*Please note this checklist **should be used in conjunction with** the "**IRB EQUIP TIPS – How To Register And Update Your Study On ClinicalTrials.gov ClinicalTrial.gov**" document to help address common issues and errors noted by the ClinicalTrials.gov database (PRS) staff prior to public release.*

PROTOCOL ID **NCT#**	**RECORD OWNER**	**PI**	❑ **Registration** ❑ **Update status** ❑ **Results** *(add Results checklist)*	❑ **pACT/ACT** ❑ **Non-ACT**

DATE RELEASED	**COMMENTS DATE**	**REPLY DATE**	**DATE PUBLISHED**

GENERAL REVIEW ITEMS

- ❑ **Unique Protocol ID is the IRB number ONLY** *(No other Unique protocol ID's, IRB number in digits only, no dashes, #)*
- ❑ **Record Owner** is the PI or Research Coordinator
- ❑ 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**
- ❑ No monetary value (e.g. compensation) entered anywhere in the protocol
- ❑ 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"
- ❑ **IRB Record (in KRP) is up-to-date reflecting ClinicalTrials.gov Record:** ***If needed submit an Amendment to update the following***
  - For studies that meet the criteria for clinical trials per NIH Definition and Applicable Clinical Trials, **ClinicalTrials.gov statement is included in the Consent Form / Study Information Sheet**
  - Under "**Type of Research**" – "Does this research meet the definition of a clinical trial that requires adherence to Clinicaltrials.gov?" is marked as "YES"
  - Once obtained, **NCT# is added to this section**
  - **KRP Recruitment section** reflects ClinicalTrials.gov as a recruitment method.

PROTOCOL SECTION

STUDY IDENTIFICATION

- ❑ **Unique protocol ID is the IRB number ONLY** *(DIGITS only, no dashes, letters or #)*
- ❑ 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 Record) or **CFCCC studies**: Include additional a unique identifier

STUDY STATUS

- ❑ **Record Verification Date** is the **current month/year**
- ❑ Overall Status matches IRB Status

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- ❑ **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: Lead Researcher / Principal Investigator (PI)** for all Investigator Initiated studies at UCI [unless instructed to complete differently]
- ❑ **Sponsor:** Regardless of funding source, enter the "regulatory sponsor" (primary organization overseeing the implementation of the study), usually **University of California Irvine**.
- ❑ All sources of support from other institutions/entities included as Collaborators
- ❑ 'University of California Irvine' is identified as an affiliate

OVERSIGHT

- ❑ IND/IDE information completed (if applicable)

Verify Human Subjects Review

- ❑ Board Status as specified per IRB Record (in KRP):
- ❑ Approval Number is a valid IRB number
- ❑ Board Name: University of California Irvine IRB
- ❑ Board Affiliation: University of California Irvine
- ❑ Phone: (949) 824-8170; Email: irb@uci.edu
- ❑ Address: University of California, Irvine, Office of Research, Irvine, CA 92697-7600
- ❑ For studies that meet the criteria for clinical trials per NIH Definition and Applicable Clinical Trials, **Consent / study information sheet** contains **requisite ct.gov language**

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

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- ❑ 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 points written in full e.g. 5 hours not 5hrs, 60 minutes not 60mins, 2 years not 2yrs
- ❑ 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** listed as a primary research team contact
- ❑ Study Officials: Person responsible for overall scientific leadership of the protocol, including the study Principal Investigator.
- ❑ Organization Affiliation: Full name of the Official's organization (for UCI Researchers, its "University of California, Irvine")
- ❑ 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 individual participant data will be shared then '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)

If submission of results is required:

RESULTS SECTION

GENERAL CONSIDERATIONS:

- ❑ **REVIEW** PRS RESULTS GUIDANCE / CHECKLISTS / TEMPLATES: https://clinicaltrials.gov/submit-studies/prs-help/support-training-materials#results
- ❑ **SCALES:** Under "**Measure Description**" describe the unit of measure, the scale range, and describe what is means to have a high vs. low score.

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

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- ❑ 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

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

- ❑ Disclosure restrictions should be 'No' unless documentation is presented to the contrary

RESULTS POINT OF CONTACT

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- ❑ Responsible Party's Contact information will be public facing
- ❑ Information is correct and valid email address/phone number entered

DOCUMENT SECTION

- ❑ Documents in PDF format (will be converted to PDF/A when uploaded to PRS)
- ❑ 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)
- ❑ Each document must have a Cover Page or include the following at the top of the document:
  - ❑ Record (NCT) Number
  - ❑ Study Title
  - ❑ PI Name
  - ❑ Date of Document (Date the IRB last approved the document, must match date within actual document)
- ❑ Additional Documents: _____
- ❑ Uploaded document(s) does not include a publication

REFERENCES

- ❑ Links are verified (if applicable)

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