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

V 7.0 September 2024

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

- ❑ **RECORD VERIFICATION DATE is current Month and year**
- ❑ **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**
- ❑ 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…)
- ❑ **Secondary IDs include NIH grant #s** (verify in IRB Record) or **CFCCC studies**: Include additional a unique identifier

**This checklist was provided courtesy of Anthony Keyes MBA, PMP, Johns Hopkins University ClinicalTrials.gov Program, and revised for UCI use.

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

V 7.0 September 2024

STUDY STATUS

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

**This checklist was provided courtesy of Anthony Keyes MBA, PMP, Johns Hopkins University ClinicalTrials.gov Program, and revised for UCI use.

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 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 '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.)

**This checklist was provided courtesy of Anthony Keyes MBA, PMP, Johns Hopkins University ClinicalTrials.gov Program, and revised for UCI use.

- ❑ 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

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

**This checklist was provided courtesy of Anthony Keyes MBA, PMP, Johns Hopkins University ClinicalTrials.gov Program, and revised for UCI use.

RESULTS POINT OF CONTACT
- ❑ **Responsible Party's Contact information will be public facing**
- ❑ 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)

**This checklist was provided courtesy of Anthony Keyes MBA, PMP, Johns Hopkins University ClinicalTrials.gov Program, and revised for UCI use.