IRB EQUIP TIPS – CLINICALTRIALS.GOV RECORD REVIEW CHECKLIST**

V 5.0 June 2022

*Please note this checklist should be used in conjunction with the "**IRB EQUIP TIPS – Registering a Study in 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 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): *If needed submit an Amendment for 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" – "yes" to Does this research meet the definition of a clinical trial that requires adherence to Clinicaltrials.gov?
  - Once obtained, NCT# is added to this section
  - Recruitment section reflects ClinicalTrials.gov as a recruitment method.

PROTOCOL SECTION

STUDY IDENTIFICATION

- ❑ Unique protocol ID is the IRB# ; NCT# (CFCCC studies: Include additional a unique identifier)
- ❑ Brief Title does not include study type (e.g., Phase I, Randomized…)
- ❑ Secondary IDs include NIH grant #s (verify in IRB)

STUDY STATUS

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

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

Human Research Protections (HRP)
160 Aldrich Hall,
Irvine, California, 92697-7600
949-824-8170
IRB@research.uci.edu

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- ❑ Responsible Party: Lead Researcher / Principal Investigator (PI) for all Investigator Initiated studies at UCI [unless instructed to complete differently]
- ❑ 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 verified
- ❑ 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: 160 Aldrich Hall, 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

- ❑ 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

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- ❑ 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.)
- ❑ 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

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- ❑ 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

- ❑ Principal Investigators are NOT employed by sponsor as they are the sponsor
- ❑ Disclosure restrictions should be 'No' unless documentation is presented to the contrary

RESULTS POINT OF CONTACT

- ❑ 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)

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- ❑ 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)

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