



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.

<b>PROTOCOL ID</b>	<b>RECORD OWNER</b>	<b>PI</b>	<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
<b>NCT#</b>				
<b>DATE RELEASED</b>	<b>COMMENTS DATE</b>	<b>REPLY DATE</b>	<b>DATE PUBLISHED</b>	

**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**
  - o 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**
  - o Under “**Type of Research**” – “Does this research meet the definition of a clinical trial that requires adherence to [Clinicaltrials.gov](#)?” is marked as “YES”
  - o Once obtained, **NCT# is added to this section**
  - o **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 Keys MBA, PMP, Johns Hopkins University [ClinicalTrials.gov Program](#), and revised for UCI use.



<p><b>STUDY STATUS</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> <b>Record Verification Date</b> is the <b>current month/year</b></li> <li><input type="checkbox"/> Overall Status matches IRB Status (in KRP)</li> <li><input type="checkbox"/> <b>Completion Dates Actual/Anticipated</b> have been evaluated for accuracy</li> <li><input type="checkbox"/> If timeframes for outcomes are the same, the primary and study completion dates are identical</li> </ul>
<p><b>SPONSOR/COLLABORATORS</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> <b>Responsible Party: Lead Researcher / Principal Investigator (PI)</b> for all Investigator Initiated studies at UCI [unless instructed to complete differently]</li> <li><input type="checkbox"/> <b>Sponsor:</b> Regardless of funding source, enter the “regulatory sponsor” (primary organization overseeing the implementation of the study), usually <b>University of California Irvine</b>.</li> <li><input type="checkbox"/> All sources of support from other institutions/entities included as Collaborators</li> <li><input type="checkbox"/> ‘University of California Irvine’ is identified as an affiliate</li> </ul>
<p><b>OVERSIGHT</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> IND/IDE information completed (if applicable)</li> </ul>
<p><b>Verify Human Subjects Review</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Board Status as specified per <a href="#">IRB Record (in KRP)</a>:</li> <li><input type="checkbox"/> Approval Number is a valid IRB number</li> <li><input type="checkbox"/> Board Name: University of California Irvine IRB</li> <li><input type="checkbox"/> Board Affiliation: University of California Irvine</li> <li><input type="checkbox"/> Phone: (949) 824-8170 ; Email: <a href="mailto:irb@uci.edu">irb@uci.edu</a></li> <li><input type="checkbox"/> Address: 160 Aldrich Hall, Irvine, CA 92697-7600</li> <li><input type="checkbox"/> For studies that meet the criteria for <a href="#">clinical trials per NIH Definition</a> and <a href="#">Applicable Clinical Trials</a>, <b>Consent / study information sheet</b> contains <b>requisite ct.gov language</b></li> </ul>
<p><b>STUDY DESCRIPTION</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Brief Summary does not unnecessarily duplicate information provided for other data elements</li> <li><input type="checkbox"/> Brief Summary clearly states the study’s hypothesis or the purpose (for interventional and observational)</li> <li><input type="checkbox"/> Brief Summary and Detailed Description are written in complete sentences with no formatting errors</li> <li><input type="checkbox"/> <b>Record does not use personal pronouns:</b> “I, we, our, us, they, them, their” – becomes “the investigator(s)”; “you, your” – becomes “the participant(s)”</li> </ul>
<p><b>CONDITIONS</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Conditions/Focus of study are discrete and does not use verbs or complete sentences</li> <li><input type="checkbox"/> Keywords are not numbered or bulleted, each condition and keyword is listed individually, one per line</li> </ul>
<p><b>STUDY DESIGN</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> All required fields are completed</li> <li><input type="checkbox"/> Verify Study Design based on protocol in IRB</li> <li><input type="checkbox"/> “Allocation” marked as “N/A” for single-arm studies</li> <li><input type="checkbox"/> Enrollment number Actual/Anticipated verified</li> </ul>

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<p><b>ARMS/INTERVENTIONS</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Arm Title or Group/Cohort Label is brief and informative (even if there is only 1 arm)</li> <li><input type="checkbox"/> Interventions and intervention descriptions are entered correctly</li> <li><input type="checkbox"/> Arms/interventions are cross-referenced appropriately</li> </ul>
<p><b>OUTCOME MEASURES</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Title is specific and states <b>WHAT is being measured</b></li> <li><input type="checkbox"/> <b>only 1 variable</b> must be assessed per outcome measure</li> <li><input type="checkbox"/> Description explains <b>HOW outcome is being measured</b>, not WHY it is being measured</li> <li><input type="checkbox"/> Scoring scale name, score range, significance of upper and lower limits specified (if applicable)</li> <li><input type="checkbox"/> Unit of measure specified</li> <li><input type="checkbox"/> Time frame specified as a single time point or change between 2 time points</li> </ul> <p>INCORRECT: “Safety and Toxicity”, Description: “Safety of study drug.”  CORRECT: “<i>Safety as assessed by number of participants experiencing adverse events</i>”  Description: “<i>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)</i>”</p>
<p><b>ELIGIBILITY</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Age Limits are consistent with the Eligibility Criteria and with other parts of the record</li> <li><input type="checkbox"/> Eligibility criteria is divided into Inclusion/Exclusion criteria in bulleted format</li> </ul>
<p><b>CONTACTS/LOCATIONS</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> <b>Central Contact Person</b> listed as a primary research team contact</li> <li><input type="checkbox"/> Study Officials: Person responsible for overall scientific leadership of the protocol, including the study Principal Investigator.</li> <li><input type="checkbox"/> Organization Affiliation: Full name of the Official’s organization (for UCI Researchers, its “University of California Irvine”)</li> <li><input type="checkbox"/> All study sites specified matches IRB</li> <li><input type="checkbox"/> Recruiting status for each study site accurate (if at least one study site is recruiting then Study Status reflects “Recruiting”)</li> <li><input type="checkbox"/> Each facility is listed in a separate field</li> </ul>
<p><b>IPD Sharing Statement</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Field is completed with a ‘Yes’ or ‘No’ selection</li> <li><input type="checkbox"/> If ‘Yes’ is selected, an IPD Sharing Plan is identified</li> <li><input type="checkbox"/> The Plan to Share IPD selection is consistent with the IPD Sharing Plan Description.</li> </ul>
<p><b>REFERENCES</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Each citation is listed in a separate field (if applicable)</li> </ul>

**Add results checklist if results entry submitted.**

<b>RESULTS SECTION</b>
<p><b>PARTICIPANT FLOW</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Protocol Enrollment refers to total number of subjects who consented to protocol (including screen failures, withdrawals, etc.)</li> </ul>

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- 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



**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)