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.

<table>
<thead>
<tr>
<th>PROTOCOL ID</th>
<th>RECORD OWNER</th>
<th>PI</th>
<th>Registration</th>
<th>Update status</th>
<th>Results (add Results checklist)</th>
<th>pACT/ACT</th>
<th>Non-ACT</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCT#</td>
<td></td>
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</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>DATE RELEASED</th>
<th>COMMENTS DATE</th>
<th>REPLY DATE</th>
<th>DATE PUBLISHED</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

### 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

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

V 4.0 May 2022

- **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) 824-6068 or (949) 824-2125; 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)** |

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