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| **or-logo-stacked** | | **Institutional Review Board**  **Human Research Protections**  **Reviewer’s Checklist – Continuing Review (Short CPA)** | |
| **HS#:** **{Protocol\_no}** | | **CPA#:** {ECPA\_NUM} | | **Expiration Date:** {irb\_exp} | |
| **Lead Researcher:** {lr\_name} | | | | | |
| **Title:** {project\_title} | | | | | |

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| **HRP ADMINISTRATIVE CHECKLIST** | | | **COMMENTS** |
| Research was initially approved ***prior*** to January 21, 2019 | YES | NO | Yes: Pre-2018 Common Rule Requirements Applied  Yes: Research transitioned and 2018 Common Rule Requirements Applied  No: 2018 Common Rule Requirements Applied |
| Protocol Narrative On File | | | Version Date: |
| Consent Document(s) On File | YES | NO | \_\_\_ Consent(s) Version date(s):  \_\_\_ Assent(s) Version date(s):  \_\_\_ Study Info Sheet(s) Version date(s):  Appendix G (&O): Use of Deception  Appendix O: Waiver or Alteration of Informed Consent  Appendix P: Waiver of Written Informed Consent  Appendix Q: Use of Short Form Consent |
| Special Population(s) Identified | YES | NO | Appendix B: Pregnant Women / Neonates  Appendix C: Prisoners  Appendix D: Children  Appendix E: Cognitively Impaired / Medically Incapacitated  2018 Common Rule American Indian or Alaska Native Tribes |
| Source of Funding Identified | YES | NO | Specify: |
| Permission Letters / Off-Site Research Agreement On File | YES | NO | Specify:  Appendix A: Non-UCI Site  Appendix H: International Research  Appendix I: Field Work |
| sIRB Reliance IAA or IIA | YES | NO | Specify:  Appendix R: sIRB Review |
| PHI Accessed, Created or Disclosed | YES | NO | \_\_\_ HIPAA Authorization Form(s) received  Appendix T: Partial Waiver of HIPAA Authorization  Appendix T: Total Waiver of HIPAA Authorization |
| Other Ancillary Committee Clearances Received | YES | NO | hSCRO Approval |
| All Appendices On File | YES | NO | Appendix M: Storage of Data/Specimens for Future Research  Appendix N: Genetic Testing |
| Deviation Tracking Log Received | YES | NO |  |

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| **ADMINISTRATIVE COMMENTS FOR THE LEAD RESEARCHER (LR)** |

**REVIEWER’S CHECKLIST**

1. **Confirmation of Criteria for IRB Review and Approval:** Please review the following criteria and list any concern that you will communicate to the researcher in the corresponding comment box or in the open space below.

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| --- | --- | --- | --- | --- | --- |
| **CRITERIA FOR REVIEW** | | | | | **COMMENTS** |
| 1 | I, the reviewer, have a conflicting interest with this protocol. | YES | NO |  | *If yes, arrange for re-assignment of this protocol.* |
| 2 | Have any modifications been made without prospective UCI IRB review and approval? | YES | NO |  |  |
| 3 | Have there been any unanticipated problems or serious/continuing noncompliance that needs to be reported to the IRB? | YES | NO |  | *If yes, refer to EQUIP for review of problem.* |
| 4 | Have there been any participant complaints that need to be reported to the IRB? | YES | NO |  |  |
| 5 | Has a CT.gov registration number been provided? | YES | NO | N/A |  |
| 8 | Are human subject research trainings current for the study team? | YES | NO |  |  |
| 9 | Research continues to meet the criteria for IRB approval in accordance with 45 CRF 46.111 or the ethical standards as outlined in the Belmont Report, and UCI Policy. | YES | NO |  |  |

1. **Risk Confirmation – No more than Minimal Risk:**



Category(ies): **\_\_\_\_\_\_\_\_\_\_\_\_\_\_**



Category(ies): **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

1. **IRB Recommendation:**

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1. **IRB Review cycle:**



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| **^ Expedited or Exempt Research meets the following criteria (all must be true):** | |
| **Pre-2018 Common Rule:**   * Exempt research, regardless of funding * Expedited research not subject to federal regulations (i.e. not funded/supported by federal entities) * Not subject to FDA regulations:   + Does not involve a drug   + Not a clinical investigation of a medical device * Expedited research not under UCI expanded Category 13 | **2018 Common Rule:**   * Exempt research not funded/supported by the Department of Justice (DOJ) * Not subject to FDA regulations:   + Does not involve a drug   + Not a clinical investigation of a medical device * Expedited research not under UCI expanded Category 13 |
| \* **Please provide a rationale below if recommended review cycle is less than 3 years.** | |
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1. **Reviewer Comments:**

**Reviewer’s Signature** **Date**