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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 AppliedYes: Research transitioned and 2018 Common Rule Requirements AppliedNo: 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: ChildrenAppendix E: Cognitively Impaired / Medically Incapacitated2018 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) receivedAppendix 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 ResearchAppendix 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**