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| --- | --- | --- | --- | --- | --- |
| **or-logo-stacked** | | | **Institutional Review Board**  **Human Research Protections**  **Reviewer’s Checklist - New Study Expedited or Full Committee** | | |
| **HS#:** **{Protocol\_no}** | **APP#:** {ELECTRONIC\_APP\_NUM} |  | |  |  |
| **Lead Researcher:** {lr\_name} | | | | | |
| **Title:** {project\_title} | | | | | |

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| --- | --- | --- | --- |
| **HRP ADMINISTRATIVE CHECKLIST** | | | **COMMENTS** |
| Required Signatures Received | YES | NO | Waiting for Signatures |
| Consent Document(s) Received | YES | NO | \_\_\_ Consent(s)  \_\_\_ Assent(s)  \_\_\_ Study Info Sheet(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  American Indian or Alaska Native Tribes |
| Recruitment Material Received | YES | NO |  |
| Data Collection Instrument Received | YES | NO |  |
| Source of Funding Identified | YES | NO | Specify: |
| Permission Letters / Off-Site Research Agreement Received | YES | NO | Specify:  Appendix A: Non-UCI Site  Appendix H: International Research  Appendix I: Field Work |
| 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 |
| Referred to COIOC | YES | NO | Specify: |
| Referred for Scientific Review | YES | NO | Date: |
| Other Ancillary Committee Clearances Received | YES | NO | PRMC Approval/Exemption  hSCRO Approval  IBC Approval  RSC Approval |
| Master (Sponsor) Protocol Received | YES | NO | Version: |
| Drug / Biologic or Medical Device Identified | YES | NO | Appendix J: Drug / Biologic Study  Appendix K: Device Study |
| Investigator’s Brochure Received | YES | NO | Version: |
| All Appendices Received | YES | NO | Appendix L: Use of Placebo or Sham Procedure  Appendix M: Storage of Data/Specimens for Future Research  Appendix N: Genetic Testing  Appendix S: Data Safety Monitoring Plan |

##### HRP ADMINISTRATIVE COMMENTS

**\*\*If you have any questions or would like assistance with this review, please feel free to contact me at (949) 824-XXXX or at XXXX@uci.edu. Thanks – XXXX**

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| **ADMINISTRATIVE QUESTIONS AND NOTES FOR THE IRB** |

**Notes for the IRB:**

**Questions for the IRB:**

1. **Question** **X**?





**(Please comment as necessary):**

1. **Appendix X:** Please review Appendix X. Does the IRB agree with the information as presented?







1. **Administrative Comments:** Does the IRB agree with the Administrative Comments for the LR?





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

**UCI IRB REVIEWER’S CHECKLIST**

1. **Criteria for IRB Review and Approval:** Please review the federal criteria for IRB approval and indicate whether the research meets each criterion by checking the appropriate box. List any concern that you would like communicated to the researcher in the corresponding comment box or in the open space below.

***(Criteria for IRB approval of research in accordance with 45 CRF 46.111, 21 CFR 56.111 and UCI Policy)***

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| **CRITERIA FOR IRB REVIEW AND APPROVAL** | | | | | **COMMENTS** |
| 1 | The IRB has the expertise needed to review this research. | YES | NO |  | *If no, contact IRB staff to arrange consultation with expert.* |
| 2 | I, the IRB reviewer, have a conflicting interest with this protocol. | YES | NO |  | *If yes, contact HRP staff ASAP to arrange for re-assignment of this protocol.* |
| 3 | The statement of purpose/hypothesis is adequate. | YES | NO |  |  |
| 4 | Study personnel appear appropriate and qualified. | YES | NO |  |  |
| ***Risk/Benefit Assessment – Risks include possible physical, psychological, economic, social and legal harms.*** | | | | | |
| 5 | Risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk. | YES | NO |  |  |
| 6 | Risks to subjects are minimized, whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes. | YES | NO | N/A |  |
| 7 | Risks to subjects are reasonable in relation to both:   * anticipated benefits, if any, to subjects; and * the importance of the knowledge that may reasonably be expected to result. | YES | NO | N/ |  |
| ***Subject Selection*** | | | | | |
| 8 | Selection of subjects is equitable in relation to the purposes of the research and the setting in which the research will be conducted. | YES | NO |  |  |
| 9 | Selection of subjects (i.e., inclusion/exclusion criteria) is appropriate based on the research and the setting in which the research will be conducted. | YES | NO |  |  |
| 10 | The recruitment process minimizes the potential for undue influence or coercion. | YES | NO | N/A |  |
| 11 | Compensation - neither the amount of payment nor the proposed method and timing of disbursement is coercive or presents potential for undue influence. | YES | NO | N/A |  |
| 12 | Recruitment materials are appropriate. | YES | NO | N/A |  |
| ***Informed Consent*** | | | | | |
| 13 | Informed consent is sought from each prospective subject or the subject's legally authorized representative and appropriately documented in accordance with, and to the extent required by 45 CFR 46.116 and 45 CFR 46.117, and 21 CFR 50.25 and 21 CFR 50.27 as applicable. | YES | NO | N/A |  |
| ***Subject Protections*** | | | | | |
| 14 | The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.  *For > minimal risk studies, UCI requires investigators conducting clinical investigations to at a minimum, have a DSM plan.* | YES | NO | N/A |  |
| 15 | The research plan makes adequate provisions to protect the privacy of subjects. | YES | NO |  |  |
| 16 | The research plan makes adequate provisions to maintain the confidentiality of data. | YES | NO |  |  |
| 17 | The research **does** involve subjects likely to be vulnerable to coercion or undue influence, such as: children, prisoners, individuals with impaired decisions-making capacity, or economically / educationally disadvantaged persons.  **If YES,** the research plan **does** include additional safeguards to protect their rights and welfare. | YES  YES | NO  NO |  |  |
| 18 | Research aligns with Tribal Law when including American Indian or Alaska Native Tribes | YES | NO | N/A |  |

1. **Risk Assessment:**



If Virtually No Risk*, indicate all corresponding Category(ies)*:

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If [Minimal](http://www.rgs.uci.edu/ora/rp/hrpp/levelsofreview.htm#Expedited) Risk*, indicate all corresponding Category(ies)*:



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| **Please provide a rationale for any change in the risk assessment (e.g., from Expedited to Full Committee or vice versa).** |
|  |

1. **IRB Recommendation:**

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| **+ Please provide a rationale below if recommendation is disapprove the research.** |
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1. **IRB Review cycle:**

   \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| **^ Expedited Research meets the following criteria (all must be true):** |
| **2018 Common Rule Criteria:**   * Not subject to FDA regulations:   + Does not involve a drug   + Not a clinical investigation of a medical device * Not Expedited under UCI expanded Category 13 |
| **For Expedited Research, please provide a rationale below if recommended review cycle is less than 3 years.** |
|  |
| **For Full Committee Research, please provide a rationale below if recommended review cycle is less than 12 months.** |
|  |

1. **Reviewer Comments:**

*For Expedited Research Only – If ‘M’ by IRB, Staff will review response and administratively approve under Chair/Vice-Chair’s delegation. \_\_\_\_\_\_ (initial here)*

**Reviewer’s Signature** **Date**

Note: The information provided on this form may be preliminary and may not necessarily reflect the discussion and final decision and/or recommendation of the Committee.