|  |  |
| --- | --- |
| **or-logo-stacked** | **Institutional Review Board****Human Research Protections****Reviewer’s Checklist – Modification Request** |
| **HS#:** **{protocol\_no}** | **MOD#:**{EMOD\_NUM}  |  |  |  |  |
| **Lead Researcher:** {lr\_name} |
| **Title:** {project\_title} |

|  |  |
| --- | --- |
| **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  |
| All Necessary Documents Received | YES  | NO  | Revised Protocol Narrative |
| Special Population(s) Added | 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 |
| Permission Letters / Off-Site Research Agreement Received | YES  | NO  | Specify:  |
| 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  |

##### 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**

|  |
| --- |
| **IRB REVIEWERS:** Please review the requested modifications to the protocol and address any concerns the HRP staff has raised. The focus of the current review should be on the requested revisions, unless the submission contains a policy or regulatoryproblem. |

##### SUBJECT ACCRUAL SUMMARY

|  |  |
| --- | --- |
| IRB Approved Sample Size: |  |
| Number of Subjects Enrolled To Date: |  |
| Number of Subjects Currently Receiving Active Research Intervention: |  |
| Study Status (e.g., subject enrollment is yet to begin): |  |

|  |
| --- |
| **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?





**Significant New Findings (HRP staff: If the modification request appears to involve significant new findings that may relate to participants’ willingness to continue in the research; if not already addressed, contact the LR to see how they plan to notify participants and to obtain the revised consent form/letter/etc.):**

**INCLUDE THIS QUESTION IF NO NOTIFICATION DOCUMENT WAS PROVIDED**

1. **Does this modification request involve significant new findings that should be provided to participants?**





 **(Please comment as necessary):**

**If** **YES, indicate:**







**INCLUDE THIS QUESTION IF A NOTIFICATION DOCUMENT WAS PROVIDED**

1. The LR has provided the following as a plan for notification of subjects of significant new findings. Is the LR’s plan adequate?

**(Provide summary of the plan – i.e., who the LR plans to notify and how. Also provide a copy of the notification document)**





**(Specify what needs to be changed):**

|  |
| --- |
| **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 still 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)***

|  |  |
| --- | --- |
| **CRITERIA FOR IRB REVIEW AND APPROVAL OF MODIFICATION**  | **COMMENTS** |
| 1 | I, the IRB reviewer, have a conflict of interest on this protocol.  | YES | NO |  | *If yes, contact HRP staff ASAP to arrange for re-assignment of this protocol.* |
| ***Risk/Benefit Assessment*** |
| 2 | The change in the research protocol alters the risk to subjects, but the risk to benefit ratio is still acceptable.  | YES  | NO | N/A  |  |
| 3 | 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 |  |  |
| 4 | Risks to subjects will be minimized, whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes. | YES  | NO | N/A  |  |
| 5 | Risks to subjects are still 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 |  |  |
| ***Informed Consent Process*** |
| 6 | The change in the research protocol prompts a change in the consent document and the consent form has been adequately revised to reflect the change. | YES  | NO | N/A  |  |
| 7 | The change in the research protocol involves significant new findings that may affect a subject’s willingness to continue participation.If **YES,** subjects already enrolled in the study should be notified of these new findings.  | YES  YES  | NO NO  | N/A N/A  | *Note: If yes, IRB approval letter should document that re-consent (or other method of notification) is required for subjects already enrolled.*  |
| 8 | 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  |  |
| ***Additional Criteria for IRB Review and Approval***  |
| 9 | Selection of subjects is equitable.  | YES  | NO | N/A  |  |
| 10 | When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. | YES  | NO | N/A  |  |
| 11 | When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. | YES  | NO | N/A  |  |

1. **Risk Assessment:** If approved, would the proposed modifications change the risk of harm to subjects?







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

1. **IRB Recommendation:**

****

****

 

 



|  |
| --- |
| **Please provide a rationale below if recommendation is to restrict or disapprove the requested revisions to the research.** |
|  |

1. **IRB Review cycle:**

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

|  |
| --- |
| \* **Please provide a rationale below if recommended review cycle is different than current review cycle.** |
|  |

1. **Reviewer Comments:**

**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.