



CALIFORNIA RURAL INDIAN HEALTH BOARD, INC.

California Institutional Review Board Request for Research Protocol Modification

Date of Request: ____ - ____ - ____

Protocol #: ____ - ____

Date of Protocol Approval: ____ - ____ - ____

Protocol Title: _____

Principal Investigator (PI) Name/Title: _____

Source(s) of funding for the research: _____

Instructions: The PI must complete, sign, and submit this form with all required accompanying documentation via mail OR email to:

Mail: Jeffrey P. Braff, DrPH, CIP, MPS, CRIHB IRB Chair
CA Rural Indian Health Board
1020 Sundown Way Roseville, CA 95661

Email: CRIHB.IRB@crihb.org

Check the appropriate box(es) on the left and follow the instructions on the right for all changes that you are requesting.

Note: additional documentation may be required.

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| <input type="checkbox"/> Adding research activities independent from the main research protocol | Clearly describe the proposed change from the approved design, its rationale, and implications for the protocol in enough detail to allow scientific review of the request. |
| <input type="checkbox"/> Removing study activities independent from the main research protocol | *Please red line and/or highlight specific modifications, distinguishing original content from modified content in the approved protocol. If necessary, attach additional documentation to support these modifications. |
| <input type="checkbox"/> The addition or removal of study sites | Clearly explain why an additional or replacement study site is being requested and how the change will benefit the protocol. * Please red line and/or highlight specific modifications, distinguishing original content from modified content in the approved protocol. If necessary, attach additional documentation to support these modifications. |

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| <input type="checkbox"/> Change in PI and/or research staff | <p>Clearly explain why a change in PI is being requested. Include a detailed explanation of the new PI's current and proposed involvement in the protocol, qualifications to complete the work (CV), explain whether this is his/her first time being a PI, and whether the current PI will have any continued role.</p> <p>* Please red line and/or highlight specific modifications, distinguishing original content from modified content in the approved protocol. If necessary, attach additional documentation to support these modifications, including replacement PI's Collaborative Institutional Training Initiative (CITI Program) certificate of completion and CV.</p> |
| <input type="checkbox"/> New recruitment materials (e.g., flyer, script) | <p>* Please red line and/or highlight specific modifications, distinguishing original content from modified content in the approved protocol. If necessary, attach additional documentation to support these modifications.</p> |
| <input type="checkbox"/> Change (either increase or decrease) in the number of participants. | <p>* Please red line and/or highlight specific modifications, distinguishing original content from modified content in the approved protocol. If necessary, attach additional documentation to support these modifications.</p> |
| <input type="checkbox"/> Narrowing the range of the inclusion criteria | <p>* Please red line and/or highlight specific modifications, distinguishing original content from modified content in the approved protocol. If necessary, attach additional documentation to support these modifications.</p> |
| <input type="checkbox"/> Broadening the range of the exclusion criteria | <p>* Please red line and/or highlight specific modifications, distinguishing original content from modified content in the approved protocol. If necessary, attach additional documentation to support these modifications.</p> |
| <input type="checkbox"/> Changed data security procedures, data storage, data destruction, or confidentiality practices | <p>* Please red line and/or highlight specific modifications, distinguishing original content from modified content in the approved protocol. If necessary, attach additional documentation to support these modifications.</p> |

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| <input type="checkbox"/> Alternations in participant compensation or alteration of the payment schedule with proper justification | * Please red line and/or highlight specific modifications, distinguishing original content from modified content in the approved protocol. If necessary, attach additional documentation to support these modifications. |
| <input type="checkbox"/> Changes to improve the clarity of statements or to correct typographical errors, provided that such a change does not alter the content or intent of the statement | * Please red line and/or highlight specific modifications, distinguishing original content from modified content in the approved protocol. If necessary, attach additional documentation to support these modifications. |
| <input type="checkbox"/> Alterations to study activity duration or procedure | * Please red line and/or highlight specific modifications, distinguishing original content from modified content in the approved protocol. If necessary, attach additional documentation to support these modifications. |

PI Name: _____

PI Signature: _____

Date: ____