CALIFORNIA RURAL INDIAN HEALTH BOARD, INC.

CRIHB Institutional Review Board
Request for Research Approval

Date Request Submitted: __ __ ____

INSTRUCTIONS

Complete all questions on this form. Write "N/A" if not applicable.

Sign and date the HIPAA Privacy Regulations Written Assurance Agreement.

Attach a copy of any written research proposal used to obtain funding for the research, or other documentation detailing information provided in this cover page. Include all documents and procedures for obtaining Informed Consent, survey instruments, or any other tools used for data collection.

Submit this request with the required 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

Identifying Information

1. Protocol Title: _____
2. Name and Title of PI: _____
3. Have all researchers completed the CITI training requirements? ☐ YES ☐ NO

   **Please attach a copy of each researcher's CITI training Certificate of Completion.*
4. Organization Represented by PI (Tribe, Tribal Health Program, College/University, Agency): _____
5. Is this proposed project related to the completion and/or requirement of an academic degree?

   ☐ NO ☐ YES; if YES, provide school name and degree:

   _____
6. PI address: _____

   Telephone Number: (____) _____ - _____

   Email Address: _____

PLEASE ATTACH THE FULL PROJECT PROTOCOL

Research Protocol Information

7. Proposed beginning and ending dates of the protocol: From: __ __ ____ To: __ __ ____
8. Source(s) of funding for the research: _____
9. Brief description of the protocol (include questions to be investigated and objectives to be achieved):

10. Brief description of activities that affect individuals and communities that are required to participate in order for the protocol to be successful:

11. If you are requesting a waiver or partial waiver of informed consent or HIPAA Authorization, or an exemption from IRB review, please provide a clear explanation of why the proposed activity qualifies for this:

Risks, Benefits, and Privacy Protection Information

12. Describe any potential risks of the proposed activity to the individuals and communities involved:

13. Describe any potential benefits of the activity to the individuals and communities involved:

14. Briefly describe the plan for safeguarding PHI and the PHI destruction plan once the protocol is completed.

- If approved, a "Request for Continuation of Research Approval" form must be submitted 30 days before the expiration date received in the CRIHB IRB approval letter.
- If any changes are needed on an approved protocol, (i.e. research staff, flyers, scripts, or interview tools) submit a "Request for Research Protocol Modification". CRIHB's IRB must approve any modifications before they can be implemented, and any research can continue.
- At least an annual review is required by law for the IRB to review the research protocol objectives, activities, risks, benefits, written assurances, documents, and procedures for obtaining informed consent, survey instruments, or data abstraction instruments for data collection and progress reports or documents produced by the research protocol.

HIPAA Privacy Regulations Written Assurance Agreement

By signing the HIPAA Privacy Regulations Written Assurance Agreement the PI acknowledges and assures that all identifying information connected with the research protocol participant's protected health information will not be re-used or disclosed to any other person or entity, except as required by the HIPAA Privacy Regulations, for authorized oversight of the research protocol, or for other research as permitted by the Privacy Regulations and authorized by the IRB.

PI Name: _____

PI Signature: _____ Date: __ __ ____