



CALIFORNIA RURAL INDIAN HEALTH BOARD, INC.

CRIHB Institutional Review Board

Exemption Claim Form

Title of Protocol: _____

Complete this form if you believe your research protocol may be exempt from Internal Review Board (IRB) review.

Many research protocols involve studying people but are exempt from IRB review. In some cases, the interview subjects – as human beings – are not the subject of the inquiry. Instead, the research deals with the public role of these individuals. In other cases, the questions being asked are simply not sensitive, and we can reasonably claim that the research does not pose a risk of harm to subjects.

In submitting this form, you are requesting the appropriate IRB representative to grant an exemption. Only the IRB Chair or designee can make this determination.

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

Justification for Exemption

Federal law lists the following types of research as exempt from IRB review. In the Justification section below, **explain** any exemption that applies. Attach a detailed protocol for the research demonstrating the rationale for the project to be considered as exempt human subjects research and refer to the detailed protocol in the sections below:

Exemption	Justification
Research is on educational methods or evaluation in a normal educational setting.	
Research involves tests, surveys, or observations of public behavior without collecting any information to identify the subjects.	

Research involves no sensitive information (i.e., no physical, psychological, or social harm would come to the subject if he or she were identified with the information collected).	
Research involves public (elected or appointed) officials in their public roles. <i>[NEITHER NON-GOVERNMENTAL ORGANIZATION OFFICIALS NOR ACADEMIC EXPERTS COUNT: PROCEED TO IRB FORM]</i>	
Research involves publicly available information or documents. <i>[DO NOT MARK IF YOU ARE CONDUCTING ANY INTERVIEWS.]</i>	
Research involves the collection or study of existing data, documents, records AND the information is recorded by the investigator in such a manner that the subjects cannot be identified, directly or through identifiers linked to the subjects.	<i>[DO NOT USE IF YOU ARE COLLECTING ANY NEW DATA OR CONDUCTING ANY INTERVIEWS.]</i>
Research or demonstration projects evaluate, or otherwise examine public benefit or service programs.	

Examples:

<p>Research is on educational methods or evaluation in a normal educational setting.</p> <p><i>You might introduce a “pre-test” teaching methodology in one section and compare the final exam test scores of students in and not in the pre-test section.</i></p>	<p>Research involves tests, surveys, or observations of public behavior without collecting any information to identify the subjects.</p> <p><i>You can observe and record how people passing a homeless person on a Washington street react to him or her.</i></p>
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<p>Research involves no sensitive information (i.e., no physical, psychological, or social harm would come to the subject if he or she were identified with the information collected).</p> <p><i>You can ask people which brand of toothpaste they prefer and why.</i></p>	<p>Research involves public (elected or appointed) officials in their public roles.</p> <p><i>You can ask President Clinton how the Lewinsky issue is affecting his ability to govern.</i></p>
<p>Research involves publicly available information or documents.</p> <p><i>You can use Washington Post reports of leaks from the Kenneth Starr investigation.</i></p>	<p>Research involves the collection or study of existing data, documents, records AND the information is recorded by the investigator in such a manner that the subjects cannot be identified, directly or through identifiers linked to the subjects.</p> <p><i>You have access to data someone else has collected, and all demographics that would provide unique identifiers have been stripped.</i></p>
<p>Research or demonstration projects evaluate, or otherwise examine public benefit or service programs.</p> <p><i>You can accept a contract from the USDA to set up a demonstration project to test a new model for delivering WIC benefits.</i></p>	<p>Research involves taste and food quality consumer acceptance studies of wholesome food.</p> <p><i>You can have people take the “Pepsi Challenge.”</i></p>

ALL the human subjects’ components of the research MUST fall into the exempt categories.

If so, sign below averring that ALL research falls in the exempt categories:

Principal Investigator (PI) Name & Title: _____

PI Signature: _____

Date: ____ _