



CALIFORNIA RURAL INDIAN HEALTH BOARD, INC.

Application Instructions

How to Submit:

The application and supporting materials should be emailed to CRIHB.IRB@crihb.org
Subject line: "IRB Application"

Instructions:

- All correspondence about IRB decisions will be directed to the Principal Investigator.
- **Do NOT** begin data collection prior to IRB approval.
- All materials must be typed; handwritten materials will be returned.
- **Do NOT** leave a question blank on the application; write "n/a" if a question does not apply.
- If necessary, complete the addendums and submit them along with the application.
- All revisions and resubmissions must contain the original application with all tracked changes.
- The IRB **requires all personnel** involved in the research to complete the *Collaborative Institutional Training Initiative* (CITI). The principal investigator (PI) is responsible for ensuring that all research staff have completed the CITI training & that their certificate of completion is submitted with the IRB Application. **Re-training is required every two years.** All personnel must complete the Health Information Privacy and Security Course. Depending upon area of research, the Social Behavioral and Biomedical Research courses are required. For CITI training details visit the CITI website at <http://www.citiprogram.org>

*Research Staff include all individuals who will be involved in the proposed research including, but not limited to, staff that will recruit participants, obtain informed consent, administer surveys/questionnaires, and perform data analysis.

Types of IRB Review:

An IRB application submitted for review will fall into one of the categories listed below:

- 1. Full Board Review** - Approval for these studies require that the proposed research be reviewed at a convened Institutional Review Board (IRB) meeting. IRB approvals are valid for up to one year and require submission of annual renewals. Approval of any amendments/modifications are required before they can be implemented.
 - Full Board applications are reviewed at monthly IRB meetings, if and only if the application is received, at least, 11 working days prior to the meeting date.
 - Submit original application and additional materials, as needed.
- 2. Expedited Review** - These studies will be reviewed by either the entire convened IRB or one or two members of the IRB, dependent upon the determination of the IRB Chair. Approvals are valid for up to one year and *may* require submission of annual renewals (this will be determined by the IRB Chair). Approval of any amendments/modifications are required before they can be implemented.
 - Expedited Review applications take approximately 12 working days for review

once they have been submitted.

- Submit original application and additional materials, as needed.

3. Exemption Review- Research considered as minimal risk to human subjects can be determined to be exempt under federal regulations; however, the exemption review application must be submitted to the IRB for this determination. The exempt categories include certain educational practices and tests, study of archived or existing data, public service programs and food evaluation. No renewals are required for a certified exempt activity, although any amendments/modifications are required to be submitted to the IRB for approval before they can be implemented.

- Exemption Review applications take approximately 10 working days for review once they have been submitted.
- Submit original application and additional materials, as needed.

Common Mistakes to Avoid When Applying:

1. Indicating that data are anonymous when it is actually confidential (check definitions).
2. Not providing enough information as to who will have access to the data.
3. Not providing enough information as to how the data will be protected and stored.
4. Stating there are no risks involved in the activity. Even though the risks may be low, they need to be listed on the application.
5. Consent forms, surveys, or interview instruments are not attached, to the application, for review.

Definitions

ANONYMOUS DATA:

Data collected and held anonymously; it indicates that there are no identifying values that can link the information to the participant; not even the researcher could identify a specific participant. Online survey tools are typically conducted anonymously.

ASSENT:

Agreement by subjects not competent to give legally valid informed consent (e.g., children or cognitively impaired people) to participate in research.

BENEFIT:

A valued or desired outcome to the research that will be an advantage to the subjects participating. Compensation is not considered a benefit.

CONFIDENTIAL DATA:

Data collected and held confidentially; the researcher can identify the subjects. One way of identifying the subjects is to assign an identifying number or code to each participant. Additionally, any survey that takes place in a face to face environment is automatically labeled as confidential, as the researcher will know who provided the data. When data is collected confidentially, the information needs to be kept in a secure environment because the participants are identifiable.

GENERALIZABLE KNOWLEDGE:

Knowledge that could be applied to populations outside of the population or institution/organization participating in the research. This definition can vary.

Examples of activities that typically are not generalizable include:

- Biographies
- Oral histories that are designed solely to create a record of specific historical events
- Service or course evaluations, unless they can be generalized to other individuals
- Services or concepts where it is not the intention to share the results beyond any agency supporting the research
- Classroom exercises solely to fulfill course requirements or to train students in the use of particular methods or devices
- Quality assurance activities designed to continuously improve the quality or performance of a department or program where it is not the intention to share the results beyond the department or program

INFORMED CONSENT:

The knowing, legally effective consent of any individual or the individual's legally authorized representative. Such consent can be obtained only under circumstances that provide the prospective subject or representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.

INTERVENTION:

Includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

MINIMAL RISK:

A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research is not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. The definition of minimal risk for research involving prisoners differs somewhat from that given for non-institutionalized adults.

RISK:

The probability of harm or injury (physical, psychological, social or economic) occurring as a result of participation in research. Both the probability and magnitude of possible harm may vary from minimal to significant.

SIGNIFICANT RISK:

A research project's design that presents a potential for serious risk to the health, safety or welfare of the subjects.