

**California Rural Indian Health Board, Inc.**  
**Institutional Review Board (IRB) Policy**  
**Effective Date: October 2008**

**I. Purpose**

To establish an Institutional Review Board (IRB) of the California Rural Indian Health Board (CRIHB) to ensure that the rights and welfare of individuals and communities participating in research are protected. The IRB has the responsibility to review, and the authority to approve or disapprove research activities that are conducted by CRIHB staff, or that use data maintained by CRIHB. The IRB also has the authority to review documents that are produced from approved research. The IRB has the authority to establish conditions and requirements for approval to ensure that the activities and documents are both culturally sensitive and relevant to the American Indian individuals and communities who participate.

**CRIHB Statement of Values** (Approved by the CRIHB Board of Directors in July 2006):

**HEALTH CARE...We Value:**

Quality of Care: We support tribal health programs in delivery of quality comprehensive healthcare.

Customer-Orientation: We must never lose sight of the people we serve. Our services must be available, accessible, and acceptable to them.

Culturally Competent Health Care: We strive to integrate the best of both traditional medicine and western medicine within the context of our respective Indian cultures.

Traditional Health Practices: We value the return to our traditional health practices and the adoption of these into our personal and community health programs.

**SELF DETERMINATION...we value:**

Tribal Sovereignty: We are the "First Nations." We have a rich history of Tribal self-governance, with our own customs and laws and organizational structures, which we administer within the context of applicable State and Federal laws, in a government-to-government relationship.

Leadership: which has enabled us to survive, persevere, and develop as people.

Unity and Shared Inter-Tribal Pursuits: We are learning how to work together and collaborate more effectively. We have learned to set aside our own Tribal differences in order to pursue common legislative and programmatic goals through advocacy, coordinated actions and joint ventures.

Consensus Building and Collaboration: in our own organizational participation and in our collective legislation and advocacy activities.

Indians Helping Indians: Politically, we have accomplished this through the expression of self-determination. Professionally, we are committed to the recruitment, training, placement, and development of professional and non-professional personnel who are Indigenous. As a community we support each other in creating economic development opportunities to support our Tribal Health Programs.

### **TRADITIONAL CULTURE...we value:**

Cultural Heritage: It enables us to preserve our integrity as independent societies. This includes:

- Respect for our Selves
- Respect for each Other
- Respect for our Families
- Respect for our Youth
- Respect for our Elders
- Respect for our Tribes
- Harmony in our Lives

Our Land: Maintaining a harmonious relationship with our environment, which is sacred to us.

Life Experiences: which are rooted in our traditions and culture, and which we endeavor to share with our Youth.

## **II. Policy**

1. All research activities and documents involving human participants or their private or protected health information shall be reviewed and approved by the Institutional Review Board (IRB).
2. The IRB shall consist of at least 5 voting members, the CRIHB Corporate Compliance Officer and four members appointed by the CRIHB Executive Director. There should always an odd number of voting members whenever possible. There shall be a maximum term of appointment for appointed members.
3. Composition of the IRB and qualifications for membership shall meet the requirements of federal regulations.
4. The IRB shall meet at least annually. Minutes will be kept.
5. The IRB shall maintain records of its activities for a minimum of 3 years.
6. The IRB shall report serious events and non-compliance by the heads of projects with the conditions or requirements of the IRB to the Research Director and the Corporate Compliance Officer.

### III. Definitions

1. **Human Subjects** – means a living individual about whom an investigator (whether professional or student) conducting research obtains data through Intervention or Interaction with the individual, or Identifiable Private Information. [**45 CFR 46.102(f)**]
2. **Intervention** – includes both physical procedures by which data are gathered (for example, taking a blood sample) and manipulations of the subject or the subject's environment that are performed for research purposes.
3. **Interaction**- includes communication or interpersonal contact between investigator and subject.
4. **Private Information** – includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects. [**Federal Regulation 45 CFR 46.102(f)**]
5. **Protected Health Information (PHI)**– means individually identifiable health information. Identifiable refers not only to data that is explicitly linked to a particular individual (that's identified information) but also includes health information with data items which reasonably could be expected to allow individual identification [**Federal Regulation 45 CFR 164.512(i)**]
6. **Research** – means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to knowledge that can be generalized to other people. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities. [**Federal Regulation 45 CFR 46.102(d)**]

### IV. References

Federal regulations relevant to the IRB include the:

1. Protection of Human Subjects (**Title 45 Code of Federal Regulations [CFR] 46**).
2. Privacy Rule for protected health information (**45 CFR 160 and 164**).
3. Food and Drug Administration Regulations for the Protection of Human Subjects (**Title 21 CFR 50 and 56**).

### V. Procedures

**See Attachments**

**A. CRIHB IRB Procedures: Structure**

**B. CRIHB IRB Procedures: Review Process**

**California Rural Indian Health Board (CRIHB),  
Institutional Review Board (IRB)**

**Procedures**

**Attachment A:  
IRB Structure**

## **California Rural Indian Health Board (CRIHB), Institutional Review Board (IRB)**

### **Procedures: IRB Structure**

#### **I. Membership**

##### **A. Appointment of Members**

The California Rural Indian Health Board (CRIHB), Institutional Review Board (IRB) shall consist of the CRIHB Compliance Officer, and at least four (4) additional members appointed by the CRIHB Executive Director, or his/her designee. The Executive Director will designate the Chair of the IRB from the appointed members of the IRB. Appointments to the IRB will conform to composition requirements (see Part D below).

##### **B. Term of Appointment**

The CRIHB Compliance Officer is an *ex officio* voting member and has no maximum term. The maximum term of appointment of all other members, including that of Chair, will be three (3) years. A term may be renewed upon recommendation of the Chair of the IRB and approval by the Executive Director.

##### **C. Removal**

The Executive Director may remove any IRB member for cause related to conduct, attendance, or performance of assigned duties or administrative activities. Members may not be removed solely on the basis of their opinions or decisions related to matters coming before the IRB. Appeal is limited to a request for reconsideration addressed to the Executive Director.

##### **D. Composition**

###### **1. Qualifications in General**

The members of the IRB must have varying backgrounds and be sufficiently qualified through experience and expertise to promote respect for the research review process through their abilities to provide advice and counsel in protecting the rights and welfare of the individuals and communities involved in the projects. For this reason, in addition to whether members are experienced with research in terms of standards of professional conduct and practice, applicable laws and CRIHB's own by-laws ([www.crihb.org](http://www.crihb.org)), there will be consideration of the race, gender, cultural background of the members, including their sensitivity and cultural competence in relation to relevant American Indian community issues. Members must complete CRIHB IRB training (see Attachment A, Section F) in order to vote, however this requirement may be temporarily waived on an individual basis at the discretion of the IRB Chair.

###### **2. Gender**

There will be at least one male and one female voting member.

### 3. Diversity

Members should represent a variety of professional disciplines related to the types of health data projects coming before the IRB. At least one voting member will be a clinical health professional. At least one voting member will have research experience in a health related scientific area. At least one voting member will possess primary expertise in a nonscientific area.

#### Community Representation

- a. The IRB will include at least two voting members who are affiliated with a CRIHB member tribal community. One of whom may not be employed by CRIHB or one of its member clinics or tribal organizations or immediately related to anyone employed by CRIHB or one of its member clinics or tribal organizations. Their concerns should be primarily in nonscientific areas. They should also be recognized for their cultural competence in relation to California Indians.
- b. When research is reviewed dealing with a category of vulnerable participants (e.g. prisoners, children, pregnant women, and mentally disabled persons), the IRB will include in its reviewing body one or more individuals who have as a primary concern, the welfare of these participants.

### 5. Vacancies/Non Voting Members/Alternates

- a. Vacancies caused by resignation or departure of IRB members may be filled by appointment of the Executive Director upon recommendation of the Chair of the IRB. The appointment will be for the unexpired term of the vacant position. If not filled, the vacancy does not count for the basis of a quorum.
- b. The Chair of the IRB may request that additional individuals be appointed as non-voting members. They will be provided opportunity to participate in review and discussion activities, but may not vote. Their number is not counted for the basis of a quorum. The IRB Secretary shall serve as a non-voting member.
- c. The Chair of the IRB may request that an alternate serve in place of a voting member if the alternate has received all materials about the issues to be decided. A non-voting member may be appointed as an alternate. Alternates representing voting members will be so identified in the minutes.

#### E. IRB Research Support Team

The IRB Chair shall designate at least 2 IRB voting member to the Research Support Team (RST) with one member having at least 1 year experience as a CRIHB IRB voting member.

#### F. CRIHB IRB Training

Members must complete CRIHB IRB training in order to vote, however this requirement may be temporarily waived on an individual basis at the discretion of the IRB Chair. IRB members are required to attend a training involving the receipt and review of the following:

- 1) Review and discussion pertaining to historical documentation of research-related misconduct in American Indian and other communities
- 2) Most recent CRIHB IRB Policy
- 3) Federal guidelines XXX referenced in the CRIHB IRB Policy
- 4) CRIHB IRB check-list
- 5) On-line IHS IRB training course (optional)

- 6) Signed compliance statement stating that they will protect the confidentiality of all persons involved in any proposed research study as well as the opinions of CRIHB IRB members.
- 7) Signed statement stating that they have received all documents listed above,

## II. Meetings

### A. Frequency

Meetings will be held on call of the Chair not less than annually and as needed to reasonably meet need. Three members of the IRB may request a meeting be called which will promptly be scheduled by the Chair.

### B. Quorum

To take action, there must be a majority count of IRB voting members participating in the meeting. The voting members must include at least one CRIHB clinical or research health professional and one representative of a CRIHB tribal community, whose primary concerns are in nonscientific areas, who must participate in the meeting from the beginning and throughout the period of deliberation and decision. It is preferable that meetings are held in-person, however it is possible for members to participate by teleconference.

### C. Decisions

When a quorum is present and an issue presented, a majority of voting members is sufficient to decide. In cases where a consensus (unanimous) decision is not achieved, the minutes will reflect the distribution of favorable and unfavorable votes (see "Minutes" below).

### D. Guests

Non-members of the IRB may be present at meetings with the permission of the Chair of the IRB. Guests are not permitted to engage in discussion with the IRB or its members at meetings unless invited to do so by the Chair.

### E. Agenda

The general agenda for scheduled IRB meetings shall include at a minimum:

1. Review prior meeting minutes
2. Presentation of new research projects or documents for expedited review
3. Presentation of continuing research projects or documents for expedited review of modifications
4. Presentation of continuing research projects or documents for full review of modifications

5. Presentation of new or resubmitted research projects or documents for review (initial review)

## F. Minutes

The minutes of each meeting should contain at a minimum:

1. Quorum of voting members by name
2. Guests present by name
3. All actions taken by IRB
4. Results of votes on actions that do not achieve consensus: those for, against, and abstaining.
5. Written summary of discussion and controverted issues
6. Explanations of the basis for conditions imposed or changes required for approval, and for disapprovals
7. Dissenting members' reports and opinions
8. Record of IRB members' conflict of interest with statement that this member did not participate in the review except to provide requested information
9. Scheduled date and location for next meeting, if known
10. Starting and ending time of meeting

Minutes are promptly sent to all IRB members, the Executive Director of CRIHB and the Chair of the Board for CRIHB. Minutes, or portions thereof, may be provided to non-members of the IRB at the discretion of the Chair.

## III. IRB Authority and Responsibility

Under authority granted through the CRIHB Board of Directors, CRIHB Policy, and in conformity with federal regulations for the Protection of Human Subjects (**Title 45 Code of Federal Regulations [CFR] 46**), the Privacy Rule for Protected Health Information (**45 CFR 160 and 164**), and the Food and Drug Administration Regulations for the Protection of Human Subjects (**Title 21 CFR 50 and 56**), the CRIHB IRB is responsible for:

### A. Review and Approval of Research and Use of Protected Health Information

1. The IRB will have the responsibility to review, and the authority to approve or disapprove of research activities and documents that are conducted by CRIHB staff, or that use CRIHB data.
2. The IRB will have the responsibility to review, and the authority to approve or disapprove requests for exemption from review or a waiver or alteration of the Privacy Rule's Authorization requirement for uses and disclosures of protected health information [**45 CFR 164.512(i)**]. Approval of the use of protected health information results in a partial or complete Waiver of Authorization to use the information.

3. The IRB requires that the heads of all research projects obtain approval in advance for research activities that involve human participants or their protected health information. The IRB can establish conditions and requirements for approval of research activities and documents, and any use of Protected Health Information that involve CRIHB facilities, data, staff, resources, or funding. The Process for Review is described in Attachment B.

#### B. Authority to Suspend or Terminate Approval

The IRB has the authority to suspend or terminate approval of research activities or distribution of documents, or the use of Protected Health Information, that are not being conducted in accordance with IRB decisions, conditions, and requirements or that has been associated with unexpected harm to participants (**45 CFR 46.113**). Any suspension or termination of approval shall include a statement of the reasons and shall be reported to the head of the project and appropriate officials.

#### C. Durability of Disapproval, Suspension or Termination

Disapproval, or termination or suspension of a previously decided approval, or imposition of conditions or requirements for approval will not be voided or modified by any other authority if the IRB actions were the result of a process in conformance with written IRB procedures (Attachment B).

### IV. Records

#### A. Maintenance of Records

The IRB Secretary will prepare and maintain adequate documentation of IRB activities according to IRB Records regulations **45 CFR 46.115** that includes:

1. Copies of the requests for approval and their attachments, all progress reports submitted to funders, reports of injuries or other harms to participants, copies of changes in plans to protect participants or their personal health information, including revised informed consent procedures.
2. Minutes of IRB meetings
3. Records of continuing review activities.
4. Copies of all correspondence between the IRB and the heads of projects.
5. A list of currently appointed IRB members with biographical sketches including their qualifications to serve.
6. Written procedures for the IRB as required by **45 CFR 46.103(b)(4)**
7. Statements of significant new findings sent to participants as required by **45 CFR 46.116(b)(5) and, as applicable 21 CFR 56.109(B)**

#### B. Access to Records

IRB records will be maintained by the Secretary for at least (3) years after termination of the last approval period. Those records will be held in a secure location and shall be accessible for inspection and copying by current IRB members and authorized CRIHB and

federal government representatives. IRB records shall be accessible at reasonable times and in a reasonable manner, or shall be copied and forwarded when requested.

## **V. Reporting Requirements**

The IRB Chair shall be responsible for promptly reporting information to the CRIHB Corporate Compliance Officer (who will report to the CRIHB Executive Director) on the occurrence of any of the following:

- A. Serious or continuing noncompliance by heads of research projects with the conditions or requirements of the IRB
- B. Injuries or other harm to human participants
- C. Unanticipated problems involving risks to participants or others will be reported promptly
- D. Suspension or termination of IRB approval will be promptly reported to the CRIHB Research Director along with a statement of the reasons for the IRB action
- E. Allegations or evidence suggesting research misconduct will be reported promptly along with the results of IRB investigation, if any
- F. IRB minutes containing results of IRB deliberations
- G. Changes in the composition of the IRB

**Attachment B:  
California Rural Indian Health Board (CRIHB),  
Institutional Review Board (IRB)**

**Procedures**

**Attachment B:  
IRB Review Process**

**California Rural Indian Health Board (CRIHB),  
Institutional Review Board (IRB)**

**Procedures: Review Process**

**I. Initial Review**

- A. At a minimum, the request for approval to be submitted by the head of the research project to the Chair of the IRB shall consist of a cover page and required attachments. The cover page shall include:
1. The name, title and organization represented by the head of the project, as well as their contact information.
  2. A brief description of the research, including the question(s) to be investigated and objective(s) to be achieved.
  3. A brief description of the research activities that affect individuals and communities that are necessary for research.
  4. A plan to protect individuals and communities participating in the research, as well as any protected health information obtained.
  5. If approval of an exemption from IRB review, or a Waiver of Patient Authorization for use of protected health information are desired, a clear statement of why the research and the plan to protect participants and their personal health information qualifies for an exemption or waiver. The activities associated with the obtaining potential research participants (or their personal information), the informed consent process for actual participants, and the methods of obtaining information from the participants are of particular concern.
  6. A brief statement of the potential risks of the research to the individuals and communities involved in the research.
  7. A brief statement of the potential benefits of the research to the individuals and communities.
  8. A plan to destroy identifying information connected with personal health information at the earliest opportunity consistent with the conduct of research. Or if there is a health, legal or research justification for retaining the identifiers, then a plan to store the identified information in a manner that will protect personal health information from improper use or disclosure.
  9. Written assurances that identifying information connected with protected health information will not be re-used or disclosed to any other person or entity, except as required by the Privacy Rule (45 CFR 160 and 164), for authorized oversight of the research project, or for other research as permitted by the Privacy Rule.
  10. The beginning and end dates of the research project.
  11. The source(s) of funding for the research.
  12. Attached to the request for approval cover page shall be a copy of any written research proposal used to obtain funding for the research, or other document detailing information provided briefly in the cover page (including sample or scripts for obtaining informed consent of participants).
  13. A document certified by the CRIHB member Tribal Health Program (THP) representative(s) or affiliated tribal leader(s) for a THP involved in the proposed research activity that states they are aware of the research project and approve it.
- B. The Chair of the IRB or the Research Support Team will receive all requests for approval of research and determine:
1. If the request is incomplete as described above, the Chair or Research Support Team shall then notify the head of the project with the specific reasons for this decision and return the request to the head of the project.

2. If the research described in the request is exempt from IRB review with reference to criteria described in **Title 45 CFR 46.101 and Title 21 CFR 56.104** or other applicable regulation, the Chair or Research Support Team shall notify the head of the project and keep on file in IRB for at least three (3) years.
  3. If the research is qualified for Expedited Review as described in **Title 45 CFR 46.110 and Title 21 CFR 56.110** and other amendments as may be published in the Federal Register, the Chair or the Research Support Team shall put forward a copy of the request for Expedited Review by IRB members (See Part II below).
  4. If the research is appropriate for full IRB review the Chair or Research Support Team shall put forward a copy of the request for Full Review by IRB members.
  5. If request is for emergency use of an unapproved treatment or device (see Part IV).
- C. The Chair of the IRB shall send the request for approval to all IRB members with a deadline for completed review of not less than two (2) weeks from the date the materials are mailed.
1. The requests for approval shall be promptly scheduled for review at the next IRB meeting held after the due date as noted above in Part B of this Part.
  2. The Chair or any other IRB member may request expert consultation and review of any research. Results of this consultation shall be incorporated with the IRB findings, but the consultants shall not vote on the issue. Consultations may be given while a guest at an IRB meeting if so invited by the chair.
  3. IRB members involved as participants or head of the projects in research activities being considered must declare their conflict of interest and shall be excused from participation in discussion or decision unless information is requested from them by an IRB member. The conflict shall be noted in the meeting minutes.
- D. The IRB shall conduct full and deliberate discussion appropriate to each research project. General criteria for review should be provided by the Chair to the heads of research projects upon request. At a minimum these criteria will consist of:
1. Legal criteria for IRB approval of research include regulations **45 CFR 46.111 or 21 CFR 56.111** organized for the review process in the Indian Health Service IRB **45 CFR 46** checklist. The principal determinations are based on judgments of risks, confidentiality, degree of benefit, need for and quality of informed consent (**45 CFR 46.116**), 117, and special awareness of vulnerable populations as described in **45 CFR 46, subpart B, C, and D**.
  2. Legal criteria for IRB approval of waivers of authorization for the use of protected health information, and alterations thereof to reduce the chances of disclosure of personal health data through such things as de-identified datasets, limited datasets and data sharing agreements are described in *Institutional Review Boards and the HIPAA Privacy Rule*, National Institutes of Health (August 15 2003) and regulations **45 CFR 160 and 164**.

3. The determination of risk of unapproved medical devices shall also be assessed if the IRB determines significant risk of a medical device, as defined in **21 CFR 812**, the sponsor and head of the project shall be so notified. Further IRB evaluation shall await an Investigational Device Exemption (IDE) from the FDA.
  4. Ethical criteria for IRB approval of research are described in the Belmont Report, Ethical Principles and Guidelines for Protection of Human Subjects of Research by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (April 18, 1979) which is a required document for federal assurances.
  5. The CRIHB IRB shall also establish an American Indian Research Code appropriate for the special concerns and interests of American Indian individuals and communities in California. These special criteria for acceptable research shall be reviewed and approved by the CRIHB Board before they are included as criteria for approval of research. These criteria shall be added to the Indian Health Service **IRB 45 CFR 46** checklist to create a CRIHB IRB Review checklist.
- E. After full and deliberate discussion, the IRB will vote on the status of the request. Four categories of decision are possible:
1. Approve without modification.
  2. Approve with conditions or requirements. The conditions or requirements in this case are deemed not critical enough to warrant disapproval and resubmission. The IRB will request the conditions be met as a basis for approval, but the researcher may commence research without re-review by any IRB member.
  3. Disapprove. This category will be used for proposals, which, while generally sound, require review to ensure that conditions or requirements have been met before research commences.
  4. Withhold action until a specified future date.
  5. The IRB shall determine if aspects of the research activities or informed consent protocols need to be verified by methods outside the head of the project(s) reports. The IRB may require independent observers verify practices or request reports from those not directly involved in the research. The IRB's determination of this issue shall be included in the minutes along with which IRB member will assume responsibility for arranging and reporting the monitoring activity.
- F. The Chair will supply the head of the project with a summary of the IRB deliberations and reasons for disapproval, if applicable. The head of the project will be invited to resubmit the request or discuss any IRB action with as desired.
1. If the vote is not unanimous, the actual vote tally and description of basis for dissension for each dissenting member shall be presented in the minutes of the action.
  2. For approved requests (with or without conditions) the IRB members shall decide upon the frequency with which continuing review is to be conducted. Factors affecting this decision are:
    - a. Risk of the research activities
    - b. Expected duration of the research project

- c. Confidence of IRB in ability or resources of the head of the project to protect individuals and communities
- d. Consequences of adverse reaction on participant(s)
- e. Any other information available to IRB considered being relevant. In no case shall the continuing review period be more than one year (12 months) from the date of initial approval. When an appropriate review interval is agreed upon, this number shall be recorded in the minutes and reported to the researcher in the approval letter from the IRB.

## II. Expedited Review

- A. When the Research Support Team has determined that a project qualifies for expedited review, they must present all submitted materials to the Chair of the IRB. If the Chair after review and reference to **21 CFR 56.110 or 45 CFR 46.110** (if necessary) agrees, then the project will be granted expedited approval. The Chair will determine the continuing review frequency (usually one year) and the researcher shall be notified of the approval and review frequency through use of the approval letter.
- B. Research given expedited approval by the Chair of the IRB (see Part I, Part A) will be presented to the whole IRB at the next scheduled meeting. The Chair will present a summary of the project and make available to any IRB member a copy of all submitted materials.
- C. Any voting IRB member may request full IRB review of any project brought forth as expedited. If a majority of participating IRB members vote to consider the proposal as a regular full review, it shall be handled as described from Part I, Part B.
- D. If the expedited approval is overturned through IRB action noted in Part B above, the researcher shall be promptly notified by the Chair to stop all research activities until full IRB review can be accomplished.
- E. Expedited approval of research activities should never be used to circumvent the normal, full IRB process. Interim approvals should not be given to commence research pending full IRB review.
- F. Expedited review cannot be used to disapprove a project. All other full IRB actions may be accommodated by expedited review.

## III. Continuing Review

- A. All approved proposals shall have a specified frequency of review as described in Part I.
- B. The IRB log shall include a category that contains the review dates of each proposal.
- C. The IRB Secretary sends the head of the project IRB review form near the time of scheduled review.
- D. If the form is not returned to the IRB in a reasonable amount of time, the IRB Secretary will re-send the form. If not returned in several weeks, the secretary shall notify the Chair of the IRB.

- E. The Chair of the IRB shall promptly notify the head of the project by telephone if possible, by mail if not, that the IRB will consider this non-response at its next meeting and that likely IRB action will include removal of approval and reporting the action to the CRIHB Research Director. If no response is received, the issue will be discussed at the next scheduled IRB and appropriate action taken.
- F. The Chair of the IRB shall carefully consider all continuing review responses. Special attention will be given to reports of adverse events, inordinate numbers of participants refusing to participate (dropouts), changes made to the protocol not known and approved by the IRB, or significant findings which would be made known to the participants. A statistical test of significance in the latter case is to consider any finding which would influence a reasonable person to avoid participation, or to prefer one limb of the project over another as probably significant.
- G. Results of this analysis shall be brought to the IRB at its next scheduled meeting and the Chair will have available the proposal with all correspondence and approved modifications for IRB member review at the meeting. The Chair will give a brief summary of the project and make available the completed continuing review form to any IRB member.
- H. Any IRB member having a conflict of interest shall so identify and it shall be handled as for conflicts in Part I, Initial Review.
- I. After discussion and deliberation, the IRB will choose by majority vote, one of the following:
1. Approve
  2. Approve with additional conditions and appoint one member to communicate and verify
  3. Terminate or suspend research
  4. Defer judgment until a specified date that may include a request for verification from sources outside the participants in the project. The IRB will specify which member is responsible for arranging verification and reporting back to the IRB within a specified time period
- J. The period of the renewed approval shall be specified but in no case shall be greater than one (1) year.
- K. The results of the continued review will be provided to the researcher with an invitation to obtain more information if necessary from the Chair. In addition, the due date for the next review shall be provided.
- L. In cases of non-unanimous decisions, the provisions for reporting the vote tally and reasons for dissension shall be provided as noted in Part I.
- M. The IRB shall also consider whether or not significant new information is present and may require reporting this information to all participants as a condition for continued approval of the project. The new information may or may not have been generated by the research project.

#### **IV. Review of Documents**

- A. It is the responsibility of the** the head of the research project who submitted the original proposal for IRB review **to provide the IRB a chance to review document(s) produced from each approved study prior to submission for publication or public release. Examples of produced documents include but are not limited to, reports, fact sheets and other publications. The IRB shall receive the document(s) at the earliest possible time, and no later than four weeks prior to submission for publication or public release, whichever is first. Each document from the study shall be submitted to the IRB Chair to**

**ensure that the study methods to be documented are the same as those approved by that IRB and that the document(s) are both culturally sensitive and relevant to the American Indian communities who participated in the study is completed. IRB approval of the study is not complete unless the document is reviewed and consistent with the CRIHB Statement of Values prior to publication or public release. It is the responsibility of the researcher to disclose the use of existing data, non-CRIHB data as well any applicable IRB reviews associated with the use of that data.**

## **V. Emergency Use of Unapproved Treatment or Device**

A. An emergency must meet the following requirements:

1. Life threatening situation
2. No time for IRB review before use
3. No accepted or standard treatment of comparable efficacy and safety available

B. The head of a project may employ a treatment or device without IRB prior approval if an emergency as defined above applies.

C. The head of the project must notify the IRB within five (5) days of emergency use with written description of the emergency basis, the details of the treatment, the response of the patient, and whether or not further uses are expected within the next 30 days.

D. The IRB Chair shall review the head of the project's notification and determine if a special IRB meeting needs to be called to review future uses or if the material can be presented at the next scheduled IRB meeting.

E. Informed consent must be obtained in all emergency uses meeting requirements of **21 CFR 50.25** unless waiver is justified (see below).

F. The informed consent requirement may be waived under provisions of **21 CFR 50.23** which, in general, may allow administration if there not be time or opportunity to obtain consent and the situation is life threatening. The head of the project must have an independent physician corroborate the need for waiver, prospectively if possible. The IRB must be notified within five (5) days by the head of the project with written basis for waiver and include an independent physician supporting review.

## **V. IRB Log**

For internal tracking purposes, the IRB Secretary shall maintain a log of requests for approval containing at a minimum the following:

1. IRB number of project: assigned on receipt of original proposal
2. Date proposal received
3. Date proposal sent to Chair for initial review
4. Date proposal sent to CRIHB IRB members
5. Due date for completion of review by IRB members

6. Date project reviewed at IRB meeting
7. Disposition – IRB decision – if disapproved and resubmitted, proposal will keep same number but be tracked from Step 2 above
8. Date due for continuing review (maximum one year)
9. Date continuing review received
10. Date continuing review by IRB
11. Decision of IRB – cycle from Step 8-11 for each continuing review

## **VI. Special Procedures**

- A. Information sent to researchers at the start of the review process (see Part I) identifies CRIHB Area American Indian communities and statewide authorities recognized by the IRB. Researchers are invited to consult with the Chair of the IRB to identify appropriate California Area review agencies for their research. An IRB approval by itself does not constitute CRIHB member tribal approval even if some reviewing IRB members are CRIHB community tribal members.
- B. When functioning as a research approval committee for the CRIHB member communities and IRB approval is not sought or desired, the committee may base its decision on additional criteria than those outlined above. For example, appropriate use of CRIHB resources, degree of benefit to the CRIHB member tribal population, or practicality of doing the research may all become factors considered in granting approval as a research committee.
- C. The CRIHB IRB Chair or Research Support Team may postpone the review of a research proposal until a next duly scheduled meeting contingent upon verification of the following: 1) the project review and decision was made by an IHS or tribally based IRB; and 2) a certified document of the IRB review and approval is provided along with all documentation that was originally submitted by the researcher. Our IRB may require that it be informed promptly of continuing review activities, reports of significant new information, adverse reactions of research activity and may make any query into the research activity or verify those activities, as it deems necessary.
- D. The planned use of genetic material, use of genetic analysis, or establishment of continuous cell lines or other methods of producing copies of genetic material shall be prohibited unless specifically approved by the CRIHB IRB whether or not approval has been obtained from other IRB's.
- E. Any research approved by the CRIHB IRB which involves the collection or storage of biological materials (e.g., blood, serum, tissue) shall be approved only after researcher has promised in writing to fully comply with the IRB biological specimen handling protocol. In addition, the researcher shall pledge in writing to be responsible for any biological material sent to others.
- F. Significant information that may affect a research participant's interest in a project may become available. Often this is a result of continuing review activities but not always. When any IRB member knows such information (see discussion under "Continuing Review"), it shall be presented at the next scheduled meeting, and when known, the Chair of the IRB informed promptly. The IRB shall decide whether or not to require participant notification, by which this is to be done, and whether or not

verification is needed. The IRB may also require suspension or modification of the project depending on the nature of the new information.

- G. For research activities involving FDA regulated products, informed consent, if required, should contain specific notification to participants that medical records containing personal identifiers may be made available to the FDA or sponsor.