

California Tribal Epidemiology Center

Data Sharing Agreement

between

California Rural Indian Health Board (CRIHB)
as the contractor for the
California Tribal Epidemiology Center

and

[NAME]

Data Sharing Agreement

This Data Sharing Agreement (“Agreement”) is made and entered into as of the latter date signed below (the “Effective Date”) by and between the [NAME] (“Indian Health Program”) and the California Rural Indian Health Board (“CRIHB”) legal contractor for the California Tribal Epidemiology Center (“California Tribal EpiCenter”) for purposes of providing data to the California Tribal EpiCenter in compliance with the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) and implementing regulations, as they may be amended from time to time.

WITNESSETH:

WHEREAS the Patient Protection and Affordable Care Act (Public Law 111-148) includes amendments to the Indian Health Care Improvement Act at section 214(e); a provision that gives Tribal Epidemiology Centers “public health authority” status (as defined at 45 Code of Federal Regulations (CFR) §164.501) under HIPAA, and

WHEREAS the Indian Health Service (IHS) is a Health Oversight and Public Health Agency, as defined by HIPAA, and

WHEREAS IHS funds Tribal Epidemiology Centers which use patient information from IHS/Tribal/Urban service units in order to produce information regarding the health and health services of American Indians and Alaska Natives; and

WHEREAS the Tribal Epidemiology Centers are authorized by Section 214(a)(1), Public Law 94-437, Indian Health Care Improvement Act, as amended by Public Law 573; and

WHEREAS CRIHB has agreed to operate the California Tribal EpiCenter in consultation with the California Tribal EpiCenter Advisory Council; and

WHEREAS the Indian Health Program and the California Tribal EpiCenter, are committed to sharing data in order to promote the purposes of the California Tribal EpiCenter and in compliance with HIPAA, the Health Information Technology for Economic and Clinical Health (HITECH) Act and regulations promulgated there under; and

WHEREAS, the purpose of this Agreement is to satisfy the obligations of the parties under HIPAA and the HITECH Act and to ensure the availability, integrity and confidentiality of information disclosed or made available to the California Tribal EpiCenter and information that the California Tribal EpiCenter may use, disclose, receive, transmit, maintain or create from the Indian Health Program data.

NOW, THEREFORE, in consideration of the foregoing recitals and other good and valuable consideration, the recipient and sufficiency of which is hereby acknowledged, the parties agree as follows:

Definitions

Terms used but not otherwise defined in this Agreement shall have the same meaning as those terms in HIPAA.

Individual shall have the same meaning as the term ‘individual’ in 45 CFR Sect. 164.501 and shall include a person who qualifies as a personal representative in accordance with 45 CFR Sect. 164.502(g) of the Privacy Rule.

California Tribal EpiCenter shall mean the Tribal Epidemiology Center operated by CRIHB under a contract with IHS.

California Tribal EpiCenter Advisory Council, shall mean a broad-based committee to advise and support the California Tribal EpiCenter consisting of Indian Health Program community members, health care providers, and outside technical experts in epidemiology and public health.

Data Recipient shall mean California Tribal EpiCenter.

De-identified Data shall have the same meaning as the term ‘de-identified data’ in 45 CFR Sect. 164.514(a) and (b) of the Privacy Rule.

Institutional Review Board or IRB shall mean the CRIHB IRB until such time as a separate IRB is established for the California Tribal EpiCenter.

Limited Data Set shall have the same meaning as the term ‘limited data set’ in 45 CFR 164.514(e) of the Privacy Rule.

Privacy Rule shall mean the Standards for Privacy of the Individually Identifiable Information at 45 CFR Part 160 and Part 164, Subparts A and E, as amended from time to time.

Protected Health Information or PHI shall have the same meaning as the term ‘protected health information’ in 45 CFR Sect. 164.501 of the Privacy Rule, to the extent such information is created or received by the Data Recipient from the Indian Health Program.

Required by Law shall have the same meaning as the term ‘required by law’ in 45 CFR Sect. 164.501 of the Privacy Rule.

Security Rule shall mean the HIPAA Security Standards at 45 CFR Parts 160, 162, and 164.

1. Obligations of the Indian Health Program

1.1 When the Indian Health Program requests epidemiological activities requiring direct service health data, the Indian Health Program shall provide direct service health data to the California Tribal EpiCenter in the following manner, consistent with protection of the rights of individuals and tribes to confidentiality:

A. The Indian Health Program agrees to provide to the Data Recipient, copies of the data fields included in the Patient Registration and Visit export files for its clients, or

B. The Indian Health Program agrees to provide the Data Recipient, the data on computer media in format specified by the Data Recipient (e.g. Excel Spreadsheet, American

Standard Code for Information Interchange [ASCII] file) and agreed to by the Indian Health Program.

1.2 The Indian Health Program agrees to allow the Data Recipient to access the Indian Health Program's electronic data (i.e., IHS Export Reports) provided to the IHS National Patient Information Registry System including, but not limited to, demographic, workload, clinical data, and the National Data Mart data.

2. Obligations of the Data Recipient

2.1 The Data Recipient will be required to use and/or disclose the PHI only for purposes necessary to conducting epidemiological activities, or as required by law. Such uses and disclosures may include, without limitation:

- Linking data from the Indian Health Program with
 - Medicaid and Medicare program data
 - California Office of Statewide Health Planning and Development Data
 - Birth and Death Certificate data
 - Cancer Surveillance, Epidemiology and End Results (SEER) Registry
- Producing Epidemiological Reports, Issue Briefs and Fact Sheets
- Producing Epidemiological Newsletters
- Producing Epidemiological Studies related to diseases, disabilities, injuries, health care or deaths

2.2 The Data Recipient shall limit requests for PHI data to be disclosed by the Indian Health Program to the minimum information necessary to accomplish purpose(s) in connection with the California Tribal EpiCenter.

2.3 The Data Recipient agrees to use appropriate safeguards to prevent use or disclosure of PHI other than as provided for by this Agreement.

2.4 The Data Recipient acknowledges that the use of unsecured telecommunications, including the Internet, to transmit individually identifiable or deducible information is prohibited.

2.5 The Data Recipient agrees to report in writing to the Indian Health Program Privacy Official any use or disclosure of any portion of the PHI not provided for by this Agreement of which it becomes aware, including, without limitation, any disclosure to an unauthorized subcontractor or other individual within five (5) business days of its discovery.

A. The Data Recipient shall promptly investigate any alleged improper disclosure; promptly resolve any problems identified by the investigation; submit a corrective action plan with steps designed to prevent any further unauthorized disclosures; and/or require that all PHI files be returned or, if return is infeasible, destroyed immediately.

B. The Data Recipient shall provide the Indian Health Program with a copy of its findings and corrective action plan.

2.6 As legal contractor for the California Tribal EpiCenter, CRIHB agrees that it shall obtain and maintain a written agreement with any entity to whom provides PHI that will hold the entity to the same restrictions and conditions that apply thru this agreement with respect to such information. Such entities include any subcontractor who is processing data for the California Tribal EpiCenter.

2.7 The Data Recipient agrees not to contact any individual whose PHI is contained in the data it has received from the Indian Health Program.

2.8 The Data Recipient agrees to notify the Indian Health Program in writing within five (5) business days of their receipt of any court order or administrative request or subpoena for any portion of the PHI or other information provided by the Indian Health Program pursuant to this agreement. To the extent that the Indian Health Program decides to assume responsibility for challenging the validity of such request, Data Recipient will cooperate fully with the Indian Health Program in any such challenge.

2.9 The Data Recipient may disclose to other parties the minimum necessary data to conduct epidemiological studies as approved by the IRB, and in compliance with the purposes described in section 2.1 above. Wherever possible, only a Limited Data Set will be disclosed under the provisions of a Data Use Agreement entered into between Data Recipient and the other party(ies).

2.10 The Data Recipient may disclose De-Identified information to other parties without IRB approval in compliance with the purposes described in section 2.1 above. Such data may only be disclosed when approved by the Data Recipient's Corporate Compliance Officer or Privacy Officer.

2.11 The Data Recipient agrees to provide copies of any studies or reports prepared as a result of access to the Indian Health Program's data under this Agreement, and to allow the Indian Health Program to reprint or distribute same without charge, to the extent permitted under copyright protection laws and any applicable agreements as to copyright or related intellectual property rights. Such studies or reports may include:

- Epidemiological Reports, Issue Briefs and Fact Sheets
 - Community Health Profiles
 - American Indian Health in California
 - Service Utilization and Outcomes
 - Funding and Payment for Services
 - Morbidity and Mortality
- Epidemiological Newsletters
 - Morbidity and Mortality
- Epidemiological Studies related to diseases, disabilities, injuries, health care or deaths

3. Security of Data

3.1 The California Tribal EpiCenter will comply with the HIPAA Security Rule and the HITECH Act.

3.2 All reasonable precautions shall be taken by the California Tribal EpiCenter to secure the Indian Health Program's data from other individuals who are not specifically authorized access, including but not limited to the following:

- A. Data shall be kept on a password-protected file server located in a secure environment.
- B. Data will be kept in a separate directory on the server and shall be accessible only by the California Tribal EpiCenter, its Corporate Compliance Officer, Privacy Officer, Security Officer, or staff members specifically authorized access pursuant to this Agreement.
- C. Only De-identified Data, or Limited Data Sets with encrypted PHI, shall be kept behind firewalls on laptop or desktop computers, and those computers will be password-protected.

3.3 Only those individuals who are working on behalf of the California Tribal EpiCenter and who specifically require access to such data in performance of their assigned duties shall have access to these data. Access to the data will be limited to the minimum necessary data for the individual to perform the function for which the data is required. Prior to any data transfer under this Agreement, all those who will have access to the information will be notified of the use and disclosure requirements. Also prior to any transfer of any data, individuals who will have access to the data shall sign the confidentiality of patient information form.

4. Term and Termination

4.1 The provisions of this Agreement shall be effective as of the Effective Date and continue in effect for five years. The term may be automatically renewed for successive five-year terms.

4.2 The Agreement may be terminated by either party by providing written notice to the other party within the sixty (60) days prior to any renewal of the Agreement.

4.3 The Agreement shall terminate automatically if all of the PHI provided by the Indian Health Program to the Data Recipient is destroyed or returned to the Indian Health Program. If it is infeasible to return or destroy the PHI, Data Recipient shall so notify the Indian Health Program of that fact, and shall continue to extend the protections of this agreement to such information for so long as Data Recipient retains the PHI.

4.4 Upon the Indian Health Program's learning of any material breach of this Agreement by the Data Recipient, the Health Program shall provide the Data Recipient with written notice of the breach and an opportunity to cure the breach. If the Data Recipient fails to cure the breach to the satisfaction of the Indian Health Program within twenty (20) days following its receipt of notice, the Indian Health Program may thereupon immediately terminate this Agreement.

5. Indemnification

5.1 The California Tribal EpiCenter shall indemnify, defend and hold harmless the Indian Health Program, and its trustees, agents, officers, servants, and employees, and its respective successors, heirs, subcontractors and assigns ('Indemnities') from and against any claim cause of action, liability, damage, cost or expense (including, without limitation, reasonable attorney's fees and court costs) arising out of or in connection with any unauthorized or prohibited Use or Disclosure of the PHI or any other breach of this agreement by the Data Recipient or any of its subcontractors, agents or persons

under the Data Recipient's control or failure to perform the obligations hereunder by the Data Recipient, its employees, officers, volunteers, assigns, or contractors.

6. Additional Provisions

6.1 A reference in this Agreement to a section in the Privacy Rule means the section as amended or as renumbered.

6.2 The parties agree to take such action as is necessary to amend this Agreement from time to time as is necessary for the Indian Health Program and Data Recipient to comply with the requirements of HIPAA, the HITECH Act or other applicable privacy or security regulations.

6.3 Sections 2.1 and 2.3 through 2.8 of this Agreement shall survive termination of this Agreement.

6.4 Any ambiguity in this Agreement shall be resolved to permit the Indian Health Program to comply with the Privacy Rule.

6.5 There are no intended third party beneficiaries to this Agreement. Without in any way limiting the foregoing, it is the parties' specific intent that nothing contained in this Agreement gives rise or shall give rise to any right or cause of action, contractual or otherwise, in or on behalf of the individuals whose PHI is used or disclosed pursuant to this Agreement.

6.6. No provision of this Agreement may be waived except by an agreement in writing signed by the waiving party. The waiver of any term or provision shall not be construed as a waiver of any other term or provision.

6.7 The persons signing below hereby warrant that they have the right and authority to execute this Agreement and no further approvals are necessary to create a binding agreement.

6.8 This Agreement represents the entire and integrated agreement between the parties and supersedes all prior negotiations, representations or agreements, either written or oral, regarding its subject matter. Without limiting the foregoing, no provision of any other agreement or understanding between the parties limiting the liability of the Data Recipient to the Indian Health Program shall apply to the breach of any covenant in this Agreement by the Data Recipient.

6.9 This Agreement shall not be amended except through a written amendment signed by both parties hereto.

6.10 This Agreement shall be construed in accordance with and governed by the laws of the State of California.

IN WITNESS WHEREOF, the parties have executed this Agreement
APPROVED BY:

[NAME]

CALIFORNIA TRIBAL EPIDEMIOLOGY
CENTER

By: _____

By: _____

(print name)

Mark LeBeau, PhD, M.S.

Title: _____

Executive Director

Address:

California Rural Indian Health Board, Inc.
4400 Auburn Blvd., Second Floor
Sacramento, CA 95841

Date: _____

Date: _____