



JAN 24 2011

Dear Tribal Leader:

I am writing to update you on activities that the Indian Health Service (IHS) is undertaking to implement Section 130 of the Indian Health Care Improvement Act – Tribal Epidemiology Centers. Tribal Epidemiology Centers (TECs) are Tribal organizations funded by IHS to develop public health data capacity for the benefit of the Tribes they serve. In response to TECs being designated as Public Health Authorities under the IHCIA, TECs have requested access to IHS patient data for the purpose of public health surveillance and reporting on community health status for their constituent Tribes.

The IHS has worked with the TECs, in consultation with the Office of the General Counsel, Area Directors, and Chief Medical Officers, to develop a draft Data Sharing Contract (DSC) to enable the exchange of health data. The attached draft DSC is a template for agreements between TECs and the IHS for the purpose of analyzing health data. It should be noted that the draft DSC template is specifically designed to allow an authorized TEC to access only regional or Area data, and does not include individual patient identifiers or Tribal affiliation. The language in the draft DSC is designed to uphold the Health Insurance Portability and Accountability Act and Privacy Act rights of individuals and the requirements of Federal data management. Authorities negotiating these agreements at the regional level will be able to make the terms more restrictive, if desired. The IHS has developed a process for reviewing TEC requests for access to the dataset, as well as an electronic tracking system that documents what data is being accessed and what reports are being generated with the data. As always, publications that identify Tribes will require approval from those Tribes.

I am interested in your comments and suggestions on the attached draft DSC before we make it final. If you have additional input regarding the process to enable the exchange of health data between IHS and TECs, please send it by e-mail to [consultation@ihs.gov](mailto:consultation@ihs.gov) or by mail to the address below by March 24, 2011.

Thank you for your interest in this issue and your ongoing support as we move forward on implementing this section of the Indian Health Care Improvement Act.

Sincerely,

/Yvette Roubideaux/

Yvette Roubideaux, M.D., M.P.H.  
Director

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Please mail comments to:

Yvette Roubideaux, M.D., M.P.H.  
Director  
Indian Health Service  
801 Thompson Avenue, Suite 440  
Rockville, MD 20852

Enclosure

**DATA SHARING CONTRACT  
FOR THE PURPOSE OF ANALYZING  
HEALTH DATA**

**BY AND BETWEEN  
INDIAN HEALTH SERVICE  
XXX AREA  
AND  
XXX HEALTH BOARD  
XXX TRIBAL EPIDEMIOLOGY CENTER**

## **PURPOSE AND AUTHORITY**

**Section 1.01 Purpose of Contract.** This Contract is made between the Indian Health Service (“IHS”) and XXX Health Board, on behalf of the XXX Epidemiology Center (“Epidemiology Center”). The Contract establishes requirements for the retrieval of Limited Data Sets from the IHS Epidemiology Data Mart to carry out activities authorized under 25 U.S.C. § 1621m and 45 CFR § 164.514(e) but only to the extent such activities are identified in this Contract.

For purposes of IHS internal administrative needs, this Contract will carry the following identification number \_\_\_\_\_.

**Section 1.02 Grant of Authority.** The Epidemiology Center is acting under a grant from the Indian Health Service to conduct activities authorized by 25 U.S.C. § 1621m. In accordance with 25 U.S.C. § 1621m, the Epidemiology Center collects data relating to, and monitors progress made toward meeting health status objectives identified at 25 U.S.C. § 1602 using the data sets of the Indian Health Service.

**Section 1.03 Consideration.** The IHS agrees to provide the Epidemiology Center with access to Data as defined below and identified in this Contract. In exchange, the Epidemiology Center agrees to use the Data to support the Epidemiology Center’s studies, research or projects referenced in this Contract, which have been determined by the IHS to provide assistance to the IHS in monitoring, managing, and improving the IHS programs and services provided to its beneficiaries; and Epidemiology Center agrees to ensure the integrity, security, and confidentiality of the Data by complying with the terms of this Contract. The Parties acknowledge that the aforementioned consideration is both adequate and sufficient to render the Contract legally binding between the Parties.

## **DEFINITIONS**

**Section 2.01 Authorized User.** The term "Authorized User" shall mean a person with written approval by IHS (1) to access the Epidemiology Data Mart (“EDM”) on behalf of the Epidemiology Center; or (2) to access Limited Data Sets extrated from the EDM and maintained at the Epidemiology Center.

**Section 2.02 Contract.** The term “Contract” shall mean this document between the IHS and the Epidemiology Center.

**Section 2.03 Data.** The term “Data” means any information obtained from the Epidemiology Data Mart.

**Section 2.04 EDM.** The term “EDM” shall mean the Epidemiology Data Mart. The EDM is a subset of the NDW and maintained on a separate server.

**Section 2.05 HIPAA.** The term “HIPAA” means the Health Insurance Portability and Accountability Act of 1996, 42 U.S.C. §§ 1320d-2 and 1320d-4, and its implementing regulations as may be revised from time to time.

Section 2.06 Limited Data Set. The term “Limited Data Set” shall mean sets of one or more categories of Data obtained from the EDM. A Limited Data Set may contain: (a) dates of admission and discharge, as well as dates of birth and death; and (b) nine-digit zip code, city, and state information. A Limited Data Set is composed of PHI that excludes the following direct identifiers of the patient or relatives, employers, or household members of the patient: (a) names; (b) postal addresses (may retain city, state, and nine-digit zip code); (c) telephone numbers; (d) FAX numbers; (e) electronic mail addresses; (f) social security numbers; (g) medical record numbers; (h) health plan beneficiary numbers; (i) account numbers; (j) certificate/license numbers; (k) vehicle identifiers and serial numbers, including license plate numbers; (l) device identifiers and serial numbers; (m) web Uniform Resource Locators (URLs); (n) Internet Protocol (IP) address numbers; (o) biometric identifiers, including finger and voice prints; and (p) full face photographic images and/or any comparable images.

Section 2.07 Interconnection Security Agreement. An agreement established between the Parties to document the technical requirements of the interconnected IT systems. The Interconnection Security Agreement shall be attached to this Contract.

Section 2.08 NDW. The term “NDW” shall mean the National Data Warehouse (formerly known as the National Patient Information Reporting System). The “NDW” stores Data provided by the IHS and by the tribes, tribal organizations and urban Indian organizations.

Section 2.09 Parties. The term “Parties” shall mean the IHS and the Epidemiology Center.

Section 2.10 Privacy Act. The term “Privacy Act” means the Federal Privacy Act of 1974, 5 U.S.C. §552a, as amended.

Section 2.11 Privacy Rule. The term "Privacy Rule" means the Standards for Privacy of Individually Identifiable Health Information at 45 C.F.R. Parts 160 and 164, as amended.

Section 2.12 Protected Health Information ("PHI"). The term "Protected Health Information" and the abbreviation "PHI" have the same meaning as the term "protected health information" in 45 C.F.R. § 160.103. This term shall include Electronic PHI.

Section 2.13 Security Rule. The term "Security Rule" means the Security Standards for the Protection of Electronic Protected Health Information at 45 C.F.R. Parts 160 and 164, as amended.

### **EPIDEMIOLOGY CENTER ACCESS TO DATA**

Section 3.01 Limited Data Set Accessable under this Contract. Access under this Contract will include only Data from the Area or facilities that the Epidemiology Center represents.

Section 3.02 Permissible Uses of the Data by the Epidemiology Center.

- (a) The Epidemiology Center shall use the Limited Data Set only for the permitted activities described in this Contract.

- (b) The Epidemiology Center may develop, with prior written approvals from each affected tribe, tribal-specific health status reports and disseminate these reports to the respective tribal communities, IHS service units, and Area Office.
- (c) Reports will only be published outside IHS if prior written approvals have been obtained by Epidemiology Center pursuant to Section 5.12.
- (d) The Epidemiology Center shall not use Data accessed under this Contract for any purpose or in any manner that is prohibited by Federal law or, if applicable, the laws of the State of XXX or any other applicable state's laws.
- (e) The Epidemiology Center shall not disclose, use, or reuse, sell, rent, lease, loan, or otherwise grant access to the Data covered by this Contract except as specified in this Contract or as IHS shall authorize in writing. In addition, all information derived from the Data shall be subject to the same terms and conditions that apply to Data in this Contract, including Section 3.07.
- (f) The Epidemiology Center shall make every reasonable effort to limit Authorized Users' access to the Data covered by this Contract to the minimum amount of Data and minimum number of individuals necessary to achieve the purposes set forth in this Contract (i.e., individuals' access to the Data shall be on a role-based, need-to-know basis, under conditions appropriate for such access).
- (g) The Epidemiology Center agrees that the Data shall not be physically moved, transmitted, or disclosed in any way from the location of the Epidemiology Center without written approval of IHS, unless such movement, transmission or disclosure is required by law and the Epidemiology Center has previously notified IHS in writing.

Section 3.03 Access to EDM by Epidemiology Center. Epidemiology Center must obtain prior written approval from IHS for each Authorized User under its control who may access the EDM. An Interconnection Security Agreement ("ISA") between the Epidemiology Center and IHS must be in place before the Epidemiology Center's Authorized Users may access the EDM. Consistent with the ISA and based on the information provided by the Epidemiology Center, IHS shall issue a user name and password to each Authorized User who will have access to the EDM. IHS shall provide each such user name and password to the Epidemiology Center and the Epidemiology Center shall be responsible for communicating that information to the appropriate Authorized User. When the Epidemiology Center removes an individual from its list of Authorized Users, the Epidemiology Center must immediately inform IHS of the change and IHS shall cancel the user name and password of such individual as soon as reasonably possible.

Section 3.04 Epidemiology Center's Responsibility for Authorized Users. The Epidemiology Center shall be solely responsible for all of its acts and omissions and/or its Authorized Users, with respect to the EDM and/or any confidential and/or other information accessed in connection therewith, and all such acts and omissions shall be deemed to be solely the acts and omissions of the Epidemiology Center. The Epidemiology Center shall agree and ensure that:

- (a) The Data is protected in accordance with the provisions of the Privacy Rule, all applicable laws, and this Contract;
- (b) Its Authorized Users have received training, approved by IHS, regarding the confidentiality of PHI under the Privacy Rule and all applicable Federal and state laws and agree to protect the Data in compliance with the Privacy Rule, such laws and this Contract;
- (c) Its Authorized Users shall only access the EDM and use the Data for purposes as provided in this Contract;
- (d) Its Authorized Users have agreed to hold any passwords, or other means for accessing the Network, in a confidential manner and to release them to no other individual;
- (e) Its Authorized Users are informed that failure to comply with the terms of this Contract may result in exclusion from access to the EDM and use of the Data;
- (f) It has restricted access to the EDM to only the Authorized Users that the IHS has approved pursuant to Section 3.03.

Section 3.05 License. IHS grants to Epidemiology Center, and Epidemiology Center shall be deemed to have accepted a non-exclusive, nontransferable, limited right to have access to and to use the EDM, subject to the Epidemiology Center's full compliance with this Contract. IHS retains all other rights to the EDM and all the components thereof. The parties agree that the Epidemiology Center does not obtain any right, title or interest in any of the Data furnished by IHS or any information derived therefrom. IHS may condition, restrict, or cancel Epidemiology Center's access to the EDM at anytime, with or without notice.

Section 3.06 Data Disclaimer. All Data to which access is made through the EDM originates from IHS and the tribes, tribal organizations, and urban clinics. All such Data may be subject to change arising from numerous factors, such as, changes to patient PHI made at the request of the patient, changes in the patient's health condition, the passage of time, and other factors. Without limiting any other provision of this Contract, the Epidemiology Center shall be responsible for all of its actions taken or not taken resulting from or related to the use of the EDM or the Data made available thereby.

Section 3.07 Use and Disclosure of Data After Termination. When this Contract terminates, the Epidemiology Center, at the IHS' option, shall return to the IHS, or destroy, all of the IHS' Data in Epidemiology Center's possession, and keep no copies of such Data except as requested or permitted by the IHS. The IHS shall notify Epidemiology Center whether Epidemiology Center must return or destroy any Data in its possession. If the Epidemiology Center destroys any Data, then Epidemiology Center will provide the IHS with documentation evidencing such destruction. Any Data maintained by Epidemiology Center shall continue to be extended the same protections set forth in this Contract for as long as it is maintained.

Section 3.08 Reporting of Disclosure. The Epidemiology Center agrees to notify the IHS within [one day] of any uses or disclosures of the Data that are not in accordance with this

Contract and any security incidents involving the Data of which it becomes aware and to fully cooperate in the investigation of such use or disclosure. If IHS determines that the risk of harm requires notification of affected individual persons of the security breach and/or other actions, the Epidemiology Center agrees to carry out this Section without cost to IHS.

## **CONFIDENTIALITY AND SECURITY**

**Section 4.01 Confidentiality.** The Epidemiology Center agrees that it shall keep all Data obtained from the EDM confidential, in compliance with all applicable Federal and state laws, including but not limited to the Privacy Act of 1974, 5 U.S.C. 552a; Privacy Act Regulations, 45 CFR Part 5b; and Confidentiality of Alcohol and Drug Abuse Patients Records, 42 CFR Part 2.

**Section 4.02 Enforcement of Confidentiality.**

- (a) The Epidemiology Center shall report within one day to the IHS any breach of the confidentiality of the Data of which it becomes aware in accordance with Section 3.08.
- (b) The Epidemiology Center shall enforce the confidentiality provisions of this Contract by, among other possible actions, appropriately disciplining individuals within its organization who violate the confidentiality of the Data pursuant to its respective confidentiality and disciplinary policies. Such disciplinary actions may include, but not be limited to, warnings, suspensions, or termination.

**Section 4.03 Access to Confidential and Proprietary Information.** The Epidemiology Center shall not provide confidential and/or proprietary information obtained from the EDM to any tribe, tribal organization, person, or entity, and shall not publish any such information.

**Section 4.04 Security.** The Epidemiology Center shall implement security measures for the Data obtained from the EDM. Such security measures shall be no less stringent than those required by the Security Standards promulgated pursuant to HIPAA (45 CFR Parts 160 and 164).

**Section 4.05 Malicious Software, Viruses and Other Threats.** The Epidemiology Center shall ensure that its connection to and use of the EDM will not introduce any program, routine, subroutine, or data (including without limitation malicious software or “malware,” viruses, worms and/or Trojan Horses). The Epidemiology Center shall not disrupt, cause a disruption in, or permit a disruption in the proper operation of the NDW, EDM, or any part thereof or any hardware or software used by IHS in connection with the NDW and EDM.

**Section 4.06 EDM Equipment.** The Epidemiology Center shall be responsible for procuring all software, hardware, equipment, communication lines/web access, and software necessary to access the EDM. The Epidemiology Center shall be responsible for ensuring that all of its computers for interfacing with the EDM are properly and securely configured.

**Section 4.07 Connectivity.** The Epidemiology Center acknowledges that access to the EDM is to be provided over various utilities and communications lines, and Data will be transmitted over local exchange and internet carrier lines and through routers, switches, and other devices owned and maintained by third-party carriers and service providers, all of which are beyond IHS’



control. IHS assumes no liability for or relating to the integrity of any Data while it is transmitted on the connectivity lines.

Section 4.08 Use of Equipment. The equipment used by the Epidemiology Center shall not be used in any way that interferes with NDW activity. The Epidemiology Center shall be solely responsible for any damage to hardware, software, or a computer system, loss of data, and any damage to the NDW caused by it or its Authorized Users.

Section 4.09 Safeguards. The Epidemiology Center shall implement all reasonable and appropriate administrative, physical and technological safeguards to prevent use or disclosure of the Data other than as provided for by this Contract. The Epidemiology Center further shall implement all administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of Data that it receives, maintains or transmits.

Section 4.10 Security Obligation. As part of its security measures, IHS will conduct periodic audits at least quarterly to confirm that the Epidemiology Center's access to the EDM corresponded with the terms of this Contract and 25 U.S.C. §1621m. Access to the EDM by the Epidemiology Center that does not correspond to this Contract or 25 U.S.C. §1621m shall be considered an unauthorized disclosure.

Section 4.11 Contact/Identification. The Epidemiology Center shall ensure that all Authorized Users agree to not identify or attempt to identify the information in the Data or contact or attempt to contact any individual who is a subject of the Data or his/her relatives, employers or household members.

## **GENERAL OPERATIONS**

Section 5.01 System Administration. IHS shall administer the NDW and EDM and may delegate any of its functions set forth in this Contract. The IHS permits the Epidemiology Center the right to retrieve Data from EDM consistent with the terms of this Contract. However, IHS retains all other rights to the NDW and all the components thereof.

Section 5.02 Indemnification. The Epidemiology Center shall indemnify, hold harmless and defend the IHS from and against any and all claims, losses, liabilities, costs and other expenses resulting from or relating to any acts or omissions of the Epidemiology Center in connection with the Data provided to the Epidemiology Center under this Contract.

Section 5.03 No Guarantees or Warranties. IHS in no way guarantees Data pursuant to this Contract and makes no warranties, express or implied, regarding the quality of any product produced under or Data provided pursuant to this Contract. Access to the EDM and the Data obtained are provided "as is" and "as available." The Epidemiology Center is responsible for any and all acts or omissions taken or made in reliance on the EDM or the Data in the EDM, including inaccurate or incomplete Data. IHS disclaims any and all liability for erroneous transmissions and loss of service resulting from communication failures by telecommunication service providers or the EDM.

Section 5.04 Compliance with Laws. The Parties to this Contract intend and in good faith believe that this Contract complies with all Federal and state laws. The Parties agree that Federal law shall apply to any problem or dispute arising out of the Contract.

Section 5.05 Severability. If any provision of this Contract is declared void by a court or arbitrator, or rendered invalid by any law or regulation, that portion shall be severed from this Contract, and the remaining provisions shall remain in effect, unless the effect of the severance would be to substantially alter the Contract or obligations of the Parties, in which case the Parties agree to attempt in good faith to renegotiate the Contract to comply with such law(s) to the satisfaction of the Parties.

Section 5.06 Relationship of the Parties. The Epidemiology Center is acting under a grant from IHS. The Parties mutually understand and agree that in performing their respective duties and obligations hereunder, the Parties are at all other times acting as separate entities with respect to each other. Nothing in this Contract shall constitute or be construed to create a business associate arrangement, partnership, joint venture, an agency relationship, or any form of organized health care arrangement between the Parties.

Section 5.07 Force Majeure. Neither Party shall be deemed in violation of this Contract if it is prevented from performing any of its obligations by reason of: (a) severe weather and storms; (b) earthquakes or other natural occurrences; (c) power failures; (d) nuclear or other civil or military emergencies; (e) acts of legislative, judicial, executive, or administrative authorities; or (f) any other circumstances that are not within its reasonable control.

Section 5.08 Disputes. The Parties acknowledge that this Contract is not a contract or any other form of agreement entered into under the Indian Self-Determination and Education Assistance Act, P.L. 93-638, as amended, and is not subject to the dispute procedures identified therein.

Section 5.09 Criminal Penalties. The Epidemiology Center acknowledges that criminal penalties under §1106(a) of the Social Security Act (42 U.S.C. § 1306(a)), including a fine not exceeding \$10,000 or imprisonment not exceeding 5 years, or both, may apply to disclosures of information that are covered by § 1106 and that are not authorized by regulation or by Federal law. The Epidemiology Center further acknowledges that criminal penalties under the Privacy Act (5 U.S.C. § 552a(i) (3)) may apply if it is determined that the any person designated as an Authorized User by the Epidemiology Center, knowingly and willfully obtained data under false pretenses. Finally, the Epidemiology Center acknowledges that criminal penalties may be imposed under 18 U.S.C. § 641 if it is determined that its Authorized User, has taken or converted to his own use Data Set(s).

Section 5.10 Breach. The Epidemiology Center acknowledges that any breach of this Contract, including unauthorized use of the Limited Data Set(s) identified herein, may, at the discretion of IHS, result in immediate termination of this Contract. The Epidemiology Center also acknowledges that any breach of this Contract could result in further action up to and including the termination of the grant awarded under the Epidemiology Grant Program for American Indians/Alaska Natives and Urban Indian communities.

Section 5.11 No Third Party Beneficiaries. Nothing express or implied in this Contract is intended or shall be deemed to confer upon any individual or entity other than the Parties, any rights, obligations, remedies or liabilities. The Epidemiology Center does not have the right to assign or transfer their rights to any third party, including agents and subcontractors, under this Contract.

Section 5.12 Publication. IHS may require approval for any publication by the Epidemiology Center. If IHS informs the Epidemiology Center that a specific topic requires approval, any proposed publication shall be provided to the IHS for review at least sixty (60) days prior to the submission. In the event written approval is obtained, published materials shall clearly state that the opinions or assertions contained therein are those of the author and do not reflect any official or unofficial view or opinion of the IHS. Additionally, no such materials shall infringe upon, violate, or otherwise compromise patient's rights to privacy under the Privacy Act, the Privacy Rule and any other applicable Federal or state law. In no event will approval be given unless all identifiers as outlined in 45 CFR 164.514(b)(2)(i) are removed. Publications that specifically name a Tribe must receive prior approval from that Tribe.

Section 5.13 Publicity. Neither Party shall use the name of the other Party in any publicity, advertising, or new release without the prior written approval of the authorized representative of the other Party.

Section 5.14 Contact information: The designation contact point for each Party under this Contract shall be:

For the Indian Health Service:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
Telephone \_\_\_\_\_

For the Epidemiology Center:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
Telephone \_\_\_\_\_

Section 5.15 Non-waiver. Any failure or delay by IHS to enforce a provision of this Contract shall not be deemed a waiver of any provision of this Contract and any remedies thereto.

Section 5.16 Amendment. This Contract may be amended only by mutual written agreement, signed by an authorized representative of each Party.

Section 5.17 Entirety of Contract. It is expressly agreed that this written Contract represents the entire understanding between the Parties and supersedes any and all prior agreements or understanding with respect to the subject matter herein.

Section 5.18 Term and Termination of the Contract. This Contract will be effective upon the latest signatory date below and shall remain in effect for one (1) year or until terminated in writing, by an authorized representative of either Party, with or without cause. This Contract shall hereafter automatically renew annually for one year only if the Epidemiology Center grant remains in effect, the projects set forth herein are still active/ongoing, and the Data will continue to be used for the original project purpose. Otherwise, this Contract must be modified or a new contract must be negotiated.

IN WITNESS WHEREOF: the Parties hereto have duly executed this Contract in accordance with the terms and provisions contained herein. The persons signing this Contract warrant that they have full authority to do so and that their signatures shall bind the Parties for which they sign.

**For the EPIDEMIOLOGY CENTER:**

By: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

**For the INDIAN HEALTH SERVICE:**

By: \_\_\_\_\_

Name: Director, or Designee \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

By: \_\_\_\_\_

Name: \_\_\_\_\_

Title: Area Director

Date: \_\_\_\_\_