

Appendix D: Data Use Agreement (DUA) Samples

Indian Health Service
Rockville MD 20852

MAY 4 2012

Dear Tribal Leader:

The purpose of this letter is to update you on the status of efforts to develop a Data Sharing Agreement (DSA) template between Tribal Epidemiology Centers (TECs) and the Indian Health Service (IHS).

Following input received during the 2007 Department of Health and Human Services Tribal consultation session, a TEC DSA template was developed to standardize data sharing agreements between TECs and their respective IHS Area Offices and ensure regulatory compliance with the Health Insurance Portability and Accountability Act (HIPAA) and Privacy Act.

The DSA template provides access by TECs to de-identified data from IHS Epidemiology Data Mart/National Data Warehouse for public health surveillance purposes and enables Tribe-specific reporting on community health status.

The Agency has initiated a number of Tribal consultation processes to solicit input from Tribes on basic principles of data stewardship and management. Thank you for your comments and submissions in response to the January 24, 2011 Tribal Leader Letter, the July 6, 2011 Tribal Consultation Summit, and the March 13, 2012 Tribal Consultation Summit. We have incorporated your comments into the enclosed TEC DSA template (see enclosure).

This TEC DSA template is for use as a starting point for negotiations between TECs and their respective IHS Area Offices on data sharing related to the IHS Epidemiology Data Mart/National Data Warehouse. I encourage you or your staff to meet with TEC leadership to address any additional concerns arising from the data sharing process. Based on the input received to date, we plan to initiate future consultations and discussions on other types of data sharing arrangements and agreements.

Thank you for your guidance and recommendations.

Sincerely,

/Yvette Roubideaux/

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

Enclosure: TEC DSA Template

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

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

PURPOSE AND AUTHORITY

Section 1.01 Purpose of Contract. This Contract is made between the Indian Health Service (“IHS”) and Tribal 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. This agreement serves as verification of a grant of authority from the Indian Health Service for the Epidemiology Center to conduct the public health activities described herein, acting as a public health authority pursuant to the Standards for Privacy of Individually Identifiable Health Information promulgated under the Health Insurance Portability and Accountability Act (HIPAA) [45 CFR Parts 160 and 164].

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 extracted 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.

Section 2.14 Tribe. The term “Tribe” means any Indian or Alaska Native tribe, band, nation, pueblo, village or community that the Secretary of the Interior acknowledges to exist as an Indian tribe.

EPIDEMIOLOGY CENTER ACCESS TO DATA

Section 3.01 Limited Data Set Accessable under this Contract. Access under this Contract will include (1) only Data from the Area or facilities that the Epidemiology Center represents and (2) a provided statistical sample of national Data used for comparisons.

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 or the scope of work of the cooperative agreement.
- (b) The Epidemiology Center may develop tribal-specific health status reports and disseminate these reports to the respective tribal communities, IHS service units, and Area Office, with prior written approval from the specifically affected tribe. The Epidemiology Center may develop area-wide health status reports without specific tribal approval.
- (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 (1) 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 other than the Limited Data Set.

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: _____

Title: Director, Office of Public Health Support

Date: _____

By: _____

Name: _____

Title: Area Director

Date: _____

**PILOT PROJECT
DATA USE AGREEMENT
FOR THE PURPOSE OF ANALYZING
HEALTH DATA**

**BY AND BETWEEN
INDIAN HEALTH SERVICE
AND
TRIBAL EPIDEMIOLOGY CENTER**

PURPOSE AND AUTHORITY

Section 1.01 Purpose of Agreement. This Agreement is made between the Indian Health Service (“IHS”) and the ___ Tribal Epidemiology Center (“Epidemiology Center”). The Agreement addresses the conditions under which IHS will disclose and the Epidemiology Center will obtain, use, reuse, and disclose certain IHS Data Sets (including Protected Health Information) to carry out activities authorized under 25 U.S.C. § 1621m, but only to the extent such activities are identified in this Agreement.

Section 1.02 Authority. The Epidemiology Center is acting under a grant from the IHS 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. Epidemiology centers are treated as public health authorities (as defined in 45 C.F.R. § 164.501) for the purpose of the Health Insurance Portability and Accountability Act of 1996 (HIPAA)(Public Law 104–191; 110 Stat. 1936), when the Epidemiology Center is operating pursuant to a grant awarded under 25 U.S.C. § 1621m to conduct research or prevent or control disease, injury, or disability. The HIPAA privacy rule permits a covered entity to disclose protected health information to public health authorities for public health activities, without patient authorization or an opportunity to agree/object. See 45 C.F.R. § 164.512(b)(1)(i). IHS stores medical, health and billing records in a Privacy Act system of records and discloses data from this system to Epidemiology Centers pursuant to a Routine Use. See 5 U.S.C. § 552a(b)(3); IHS Medical, Health, and Billing Records, System No. 09–17–0001, System of Records Notice, Routine Use #10.

Section 1.03 Consideration. The IHS agrees to provide the Epidemiology Center with access to the Data Sets identified in Exhibit A, attached hereto and incorporated herein. In exchange, the Epidemiology Center agrees to (1) use the Data for the sole purpose of supporting the Epidemiology Center’s Public Health activities described in Section 3.02, and (2) ensure the integrity, security, and confidentiality of the Data by complying with the terms of this Agreement and applicable law. The Parties acknowledge that the aforementioned consideration is both adequate and sufficient to render the Agreement 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 National Data Warehouse (NDW) on behalf of the Epidemiology Center; or (2) to access Data Sets extracted from the NDW and maintained at the Epidemiology Center.

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

Section 2.03 Data. The term “Data” or “Data Sets” means any information disclosed under the terms of this Agreement, including but not limited to Protected Health Information (PHI), individually identifiable information, and De-identified information.

Section 2.04 Data Set(s). The term “Data Sets” shall mean sets of one or more categories of Data disclosed under the terms of this Agreement and may include Data with direct personal identifiers.

Section 2.05 De-identified. The term “De-identified” shall mean Data that does not identify an individual and with respect to which there is no reasonable basis to believe that the Data can be used to identify an individual consistent with 45 C.F.R. 164.514.

Section 2.06 Grant. For purposes of this Agreement, the term “grant” shall mean a grant or cooperative agreement awarded by the IHS under the Epidemiology Centers Program authority, 25 U.S.C. § 1621m.

Section 2.07 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 2.08 Individually identifiable health information (“IIHI”). The term “individually identifiable health information” and the abbreviation “IIHI” have the same meaning as the term “individually identifiable health information” in 45 C.F.R. § 160.103.

Section 2.09 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 2.10 Parties. The term “Parties” shall mean the IHS and the Epidemiology Center.

Section 2.11 Privacy Act. The term “Privacy Act” means the Federal Privacy Act of 1974, 5 U.S.C. §552a, as amended.

Section 2.12 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 2.13 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 2.14 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.

Section 2.15 Tracking Document. A Tracking Document is a document that identifies each data access event by the Epidemiology Center, the person who accesses the data, the purpose for which the information is to be used, and the final disposition of the data. The Tracking Document supports IHS oversight of the proposed activity. Each Tracking Document shall be

incorporated into and subject to all of the terms and conditions of this Agreement. Data provided in the document will include, at a minimum: (i) Number of linkages conducted; (ii) date ranges examined; (iii) which outside data sets were linked; and, (iv) percent race misidentification found in linked data sets.

Section 2.16 Tribe. The term “Tribe” means any Indian or Alaska Native tribe, band, nation, pueblo, village or community that the Secretary of the Interior acknowledges to exist as an Indian tribe.

EPIDEMIOLOGY CENTER ACCESS TO DATA

Authorized Users shall log data use in the Tracking Document for each primary, standalone linkage activity that utilizes the Data Set(s). Subsequent use and/or analyses of derivative de-identified datasets that do not incorporate the Data Set(s) disclosed under the terms of this Agreement do not need to be logged in the Tracking Document. The Tracking Document shall be provided to the IHS upon request but no less than twice annually and incorporated into and subject to the terms of this Agreement.

Section 3.01 Data Set(s) Accessible under this Agreement. Data provided under the terms of this Agreement will be extracted from the NDW and will only include Data from the Area or facilities for which the Epidemiology Center has geographic purview (i.e., IHS Area). The contents of the Data Set(s) are described in Exhibit A, attached hereto and incorporated herein. The Data will be transferred from IHS to the Epidemiology Center through the Secure Data Transfer Service or an equivalent encrypted system.

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

- (a) A Data Set containing PHI will be provided to the Epidemiology Center in accordance with this Agreement. The Epidemiology Center shall use the Data Set only for the public health activities described in this section.
- (b) The sole purpose of this Data Set will be limited to the following public health activity: to perform data linkages with outside sources to correct these sources for racial misclassification using the identifying information on IHS users as positive confirmation for American Indian/Alaska Native (AI/AN) race. The improved accuracy of these sources will contribute to research and the prevention or control of disease, injury, or disability.
 - a. The Data Set provided for this activity may not be used for any other purpose.
 - b. Unless explicitly authorized by this Agreement, the Data Set may not be used for any purpose set forth in a data use agreement between IHS and the Epidemiology Center that relates to limited data sets.
 - c. The Data Set may not be combined with data from the IHS Epidemiology Data Mart for purposes outside of the above activity.

- (c) The Epidemiology Center agrees that the information received through this Agreement shall not be used for any purposes that would qualify as a “matching program” under 5 U.S.C. 552a. Permitted activities include:
 - a. matches performed to produce aggregate statistical data without any personal identifiers;
 - b. matches performed to support any research or statistical project, the specific data of which may not be used to make decisions concerning the rights, benefits, or privileges of specific individuals;
- (d) The Epidemiology Center shall not develop reports using the Data Sets provided under this Agreement, but nothing in this Agreement shall prevent the Epidemiology Center from using the corrected data from outside sources to 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. The Epidemiology Center may develop area-wide or state-specific health status reports without specific tribal approval using sources other than the Data Sets provided under this Agreement.
- (e) The Epidemiology Center shall ensure that all reports developed under Section 3.02(d), above, are De-identified as per 45 CFR 164.514(b)(1) or (b)(2) before the Epidemiology Center discloses the Data.
- (f) The Epidemiology Center shall not disclose, use, or reuse, sell, rent, lease, loan, or otherwise grant access to the Data covered by this Agreement except as specified in this Agreement or as IHS shall authorize in writing.
- (g) The Epidemiology Center shall make every reasonable effort to limit Authorized Users’ access to the Data covered by this Agreement to the minimum amount of Data and minimum number of individuals necessary to achieve the purposes set forth in this Agreement (i.e., individuals’ access to the Data shall be on a role-based, need-to-know basis, under conditions appropriate for such access).
- (h) The Epidemiology Center will adhere to IHS standards of conduct for all use of this data in electronic and other formats including not sharing the Data or subsets of the Data through unsecured email.

Section 3.03 Access to EDM by Epidemiology Center. Only IHS may approve Authorized Users of the Data Set. Epidemiology Centers will request approval for new Authorized Users through a letter addressed to their Program Officer. The request letter must include a description of the User’s role with the organization and his/her anticipated tasks relevant to this Agreement. When the Epidemiology Center removes an individual from its list of Authorized Users, the Epidemiology Center must notify IHS and include disposition of Data Set(s) and derivatives accessed and/or used by the former Authorized User within 30 days.

Section 3.04 Epidemiology Center's Responsibility for Authorized Users. The Epidemiology Center must obtain prior written approval from IHS for each Authorized User under its control who may access the Data Sets. The Epidemiology Center shall be solely responsible for all acts and omissions of the Epidemiology Center and/or its Authorized Users, with respect to the any confidential and/or other information accessed in connection with this Agreement, 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 Agreement;
- (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 Agreement. This should include 42 CFR Part 2, HIPAA, and Privacy Awareness Training and annual ISSA training;
- (c) Its Authorized Users shall only access and use the Data for purposes as provided in this Agreement;
- (d) Its Authorized Users have agreed to hold any passwords, or other means for accessing the Data, 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 Agreement may result in exclusion from access to the Data and/or the NDW;
- (f) It has restricted access to the Data to only the Authorized Users that the IHS has approved.

Section 3.05 Data Disclaimer. All Data in the NDW 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 IHI 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 Agreement, the Epidemiology Center shall be responsible for all of its actions taken or not taken resulting from or related to the use of the Data made available under the terms of this Agreement.

Section 3.06 Use and Disclosure of Data After Termination. When this Agreement 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 Agreement for as long as it is maintained.

Section 3.07 Reporting of Disclosure. The Epidemiology Center agrees to notify the IHS within one (1) hour of the discovery of any uses or disclosures of the Data that are not in

accordance with this Agreement and any security incidents involving the Data of which it becomes aware and to fully cooperate in the investigation of such use or disclosure. Notification should be directly to the Division of Epidemiology and Disease Prevention Tribal Epidemiology Centers Program and the IHS Incident Response Team (IRT). If IHS determines that the risk of harm requires notification of affected individual persons of any breach and/or other actions, the Epidemiology Center agrees to carry out this Section without cost to IHS.

Notification will be sent to the IHS IRT: Email: IRT@ihs.gov; Business Hours: 1-888-830-7280 (OIT Help Desk). After Hours: 702-562-8201 (NOSC). An incident reporting form is available at https://www.ihs.gov/employeeresources/includes/themes/responsive2017/display_objects/documents/F07-02b_IRF.pdf

CONFIDENTIALITY AND SECURITY

Section 4.01 Confidentiality. The Epidemiology Center agrees that it shall keep all Data obtained under this Agreement confidential, in compliance with all applicable Federal and state laws and the terms of this Agreement.

Section 4.02 Enforcement of Confidentiality.

- (a) The Epidemiology Center shall report within one hour to the IHS any breach of the confidentiality of the Data of which it becomes aware in accordance with this Agreement.
- (b) The Epidemiology Center shall enforce the confidentiality provisions of this Agreement 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.

Section 4.03 Access to Confidential Information. The Epidemiology Center shall not provide confidential information obtained under this Agreement to any tribe, tribal organization, person, or entity, and shall not publish any such information, except as explicitly allowed in this Agreement.

Section 4.04 Security. The Epidemiology Center shall implement security measures to protect the Data Set(s) obtained under this Agreement. 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). Epidemiology Center will ensure that information used, stored, or transmitted is protected commensurate with the risk and magnitude of the harm that could result from the unauthorized access, use, disclosure, disruption, modification, or destruction of the information. FIPS-200 and associated National Institute of Standards and Technology (NIST) Special Publications, including NIST Special Publication 800-53, will be used to determine required controls according to the information categorization defined in Section 4.2. FIPS 140-2 validated cryptographic modules will be used when such controls are required.

Section 4.05 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 Agreement. 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 4.06 Data Security. Epidemiology Center agrees to store printed or imaged IHS data in a locked filing cabinet within a restricted area that is accessible only to individuals authorized pursuant to this Agreement. Electronic data will be restricted to individuals authorized pursuant to this Agreement. Authorized individuals must only access electronic data using appropriate security measures such as a password-protected data security system or least privilege access.

Section 4.07 Data Destruction. Epidemiology Center agrees that when the intended purpose of the data has been fulfilled, it will dispose of the information using any or a combination of the following destruction methods: (i) removing (that is, scrubbing or purging) all electronic files from hard drives or any other storage media that contain IHS information or (ii) shredding or burning any hard copies of IHS information such that the resulting residue prevents any recovery of the data.

Section 4.08 Contact/Identification. The Epidemiology Center shall ensure that all Authorized Users agree to not 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. The IHS shall administer the NDW. The IHS permits the Epidemiology Center the right to receive Data from the NDW consistent with the terms of this Agreement. However, IHS retains all other rights to the NDW and all the components thereof.

Section 5.02 Indemnification. The Epidemiology Center shall indemnify and hold harmless 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 Agreement.

Section 5.03 No Guarantees or Warranties. IHS in no way guarantees Data pursuant to this Agreement and makes no warranties, express or implied, regarding the quality of any product produced under or Data provided pursuant to this Agreement. 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 reports or analyses made by the Epidemiology Center using the Data that is disclosed under the terms of this Agreement, 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 NDW.

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

Section 5.05 Severability. If any provision of this Agreement is declared void by a court or arbitrator, or rendered invalid by any law or regulation, that portion shall be severed from this Agreement, and the remaining provisions shall remain in effect, unless the effect of the severance would be to substantially alter the Agreement or obligations of the Parties, in which case the Parties agree to attempt in good faith to renegotiate the Agreement 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 Agreement shall constitute or be construed to create a 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 Agreement 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 Agreement is not a contract, compact, 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 Agreement, including unauthorized use of the Data Set(s) identified herein, may, at the discretion of IHS, result in immediate termination of this Agreement. The Epidemiology Center also acknowledges that any breach of this Agreement could result in further action up to and including formal review of all data-sharing activities.

Section 5.11 No Third Party Beneficiaries. Nothing express or implied in this Agreement 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 sub-grantees, under this Agreement.

Section 5.12 Publication. IHS may require advanced review of public releases resulting from the use of IHS data. The Epidemiology Center will notify IHS of proposed topics for publication through the routine reporting process. Publicly 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 Agreement shall be:

For the Indian Health Service:

Director, DEDP
5600 Fishers Lane MS 09E10D
Rockville, MD 20857
Telephone: _____
Email: _____

For the Epidemiology Center:

Telephone _____
Email _____

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

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

Section 5.17 Entirety of Agreement. It is expressly agreed that this written Agreement 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 Agreement. This Agreement will be effective upon the latest signatory date below and shall remain in effect for one (1) year unless terminated

earlier in writing, by an authorized representative of either Party, with or without cause. After the initial one year term, this Agreement shall automatically renew annually in one-year increments not to exceed a total of three (3) years. The automatic renewal will only occur if the Epidemiology Center has an active grant with IHS, the projects set forth herein are still active/ongoing, and the Data will continue to be used for the original project purpose.

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

INDIAN HEALTH SERVICE

Signature

Date

Printed

Director, Office of Public Health Support
Title

Signature

Date

Printed

Title

EPIDEMIOLOGY CENTER

Signature

Date

Printed

Title

EXHIBIT A

DEMOGR

last_nm

first_nm

mid_nm

mail_addr_1

mail_addr_2

city_nm

state_abbr_cd

zip_code

ssn

DOB

GENDER_CD_MOD

INDIAN_STATUS_FG

ALIAS

Alias_nm_title

Alias_nm_sufx

Alias_last_nm

Alias_first_nm

Alias_mid_nm