

**Procedures and Guidance for Tribal Epidemiology Center Access to
Indian Health Service Protected Health Information
For Public Health Activities**

I. Purpose and Background

The Indian Health Service (IHS) is documenting current procedures and providing additional guidance to Tribal Epidemiology Centers (TECs) on identifying and requesting Protected Health Information (PHI) and related data from the IHS when such information is requested for public health activity purposes. This guidance and related materials will be reviewed and updated as needed to reflect any changes in policy or implementation practices. These documents are designed to provide clarity and transparency for ongoing IHS engagement with TECs on the sharing of IHS data to support their public health activities.

Treatment of TECs as Public Health Authorities

The TEC program was originally authorized by Congress within the Indian Health Care Improvement Act (IHCA) of 1992 to provide public health support to multiple tribes and urban Indian communities in each of the IHS Administrative Areas (Areas). Subsequent amendments and permanent reauthorization of the IHCA in 2010 established that TECs were to be treated as public health authorities for purposes of the Health Insurance Portability and Accountability Act (HIPAA) of 1996. As a result, the IHS may disclose PHI to TECs as public health authorities when those TECs are requesting such information for public health activities, including preventing or controlling disease, injury, or disability.

The terms PHI and data are used interchangeably throughout this document.

II. Data Available to TECs

Data Categories

- Appendix A – TEC Epidemiology Data Mart (EDM)
 - The TEC EDM is a limited PHI data set containing comprehensive electronic health record (EHR) data, including data on current patient registration, patient encounters, user population, look-up tables, and basic metadata sourced from the IHS General Data Mart (GDM). As a limited data set, certain direct identifiers for individuals are excluded from the EDM. The IHS GDM is a centralized data repository that aggregates EHR data across all submitting IHS, tribal, and urban Indian clinical sites within the Indian health system. More information about the GDM is available at <https://www.ihs.gov/npirs/>.
 - A list of data elements (variables) available within the EDM is included as Appendix A. A data dictionary available at <https://www.ihs.gov/scb/metadata/index.cfm> defines a majority of variables included within the EDM. Supplementary definitions for additional, derived variables unique to the EDM are also included in Appendix A.
- Appendix B - Personally Identifiable Data
 - Personally identifiable information (PII) is individually identifying information that includes many common identifiers (e.g., name, address, birth date, Social Security number, etc.). PII is often, but not exclusively, used for data linkage purposes to correct for racial misclassification of American Indian and Alaska Native (AI/AN) individuals in existing public health and similar data sets managed by recognized public health and similar authorities.
 - A list of data elements (variables) available to TECs is as part of the PII data table is included as Appendix B. A data dictionary defining variables is available at <https://www.ihs.gov/scb/metadata/index.cfm>.
- Additional PHI

- While the majority of IHS's data is housed within the GDM and available via the EDM, other, limited PHI may exist solely within facility-level systems. Where the data described in Appendices A & B are not sufficient to meet a specific public health purpose, the TEC may request additional PHI. In those cases, IHS will determine if suitable data are available and accessible to satisfy the request. When data are available, such requests will be processed following the procedures as outlined in this document.
- Geographic Limitations
 - TECs may only receive data reported from the IHS, Tribal, or urban Indian (I/T/U) health facilities located within the IHS Area(s) corresponding to a given TEC's geographic purview.
 - The geographic purview of any TEC that focuses solely on the health of urban Indians will include only those urban Indian health programs (UIHPs) funded through grants and contracts from the IHS, under Title V of the Indian Health Care Improvement Act.

III. Data Requests

The IHS Headquarters Office of Public Health Support (OPHS) is the Agency lead and primary point of contact for supporting TEC access to data. TECs should submit all data requests and related correspondence to OPHS via email at epidata@ihs.gov.

Please see Appendix C (Tribal Epidemiology Center PHI Request Review Process (Public Health Authority)) for a graphical overview of the data request review process and data disclosure procedures.

Request format and composition:

- Only written, formal data requests are actionable by the IHS. Requests must be in letter format on suitable organizational letterhead, signed by the TEC Director or organizational governing official, and dated within 30 calendar days of receipt by the

IHS. Electronic submission of formal requests (i.e., attachments via email) is acceptable.

- Formal requests are not required for subsequent installments of periodic data provisioning under an established, unexpired data sharing relationship or agreement (e.g., ongoing quarterly distributions of EDM data).
- Required request elements:
 - Clearly identify the data requested (e.g., Appendix A or Appendix B variables), including any applicable time period.
 - Justification for the request, including a description of the overall public health purpose of the request as well as details on how the data will be used and for what specific public health activities.
 - Attestation that the request reflects the minimum information necessary to accomplish the stated public health purpose and activities.
 - Contact information for the TEC primary point of contact for the project, including both email and phone.

IV. IHS Review and Disposition of Requests

Upon receipt of a request, OPHS will assign staff to conduct the following review steps:

- Conduct an initial review for completeness to determine if the request is actionable (i.e., properly formatted and includes all required elements). If the criteria for an actionable request are not met, OPHS will provide guidance to the requestor on actions needed to complete the request and facilitate processing.
- Assess the request for intent to develop or contribute to generalizable knowledge as research.
 - Any requests demonstrating or suggesting such intent will be referred to the appropriate Institutional Review Board (IRB) with jurisdiction for further review; OPHS will take no further action on the request within the scope of data access for public health activities.
- Determine if the request falls within the scope of any established, unexpired data sharing relationship or agreement with the requesting TEC.
 - If confirmed, OPHS will proceed with data provisioning as outlined in the

established agreement and request.

- For remaining requests not referred for IRB review or within the scope of an existing agreement, assess each actionable request based on the following criteria:
 - Congruence of the overall purpose, justification, and intended data use with public health activities;
 - The amount and type of data requested are reasonably limited to the minimum necessary to accomplish the stated public health purpose;
 - Any statutory or regulatory restrictions on sharing the requested data;
 - The availability, suitability, and accessibility of data to satisfy the request.

Once OPHS has concluded its assessment, overall assessment findings with recommendation are provided to the OPHS Director to either approve or disapprove the request via formal notification letter to the TEC.

- OPHS will submit the notification letter electronically to the requesting TEC as the formal notification and ultimate determination in response to the original data request.
 - Approval notification letters will provide guidance to the requestor on the subsequent data disclosure procedures necessary to fulfill the request.
 - Disapproval notification letters will clearly state the reason(s) for the disapproval as well as any relevant guidance for potential resubmission by the requestor.

V. Disclosure Procedures

Data Use Agreement (DUA) Required

- All approved data requests require establishment of a fully executed DUA (formerly, data sharing agreements) before a TEC can receive or access IHS data. Example DUAs accompany this guidance in Appendix D.
 - Amendment to an existing DUA to accommodate new but related requests for data may alternatively be accomplished, where appropriate.
 - DUAs will define the TEC's desired data frequency for receiving data subject to the following constraints: Appendix A data are typically generated no more frequently than quarterly; Appendix B data are typically generated no more

frequently than annually.

- OPHS will lead the development, negotiation, review, and approval processes in partnership with the requesting TEC to establish a mutually agreeable and fully approved DUA that aligns with the approved data request.
- OPHS may consult with representatives from the IHS Privacy Office, the HHS Office of General Counsel (IHS Branch), and IHS Area offices, as applicable and at a minimum, during DUA development.
- The OPHS Director and relevant IHS Area Director(s), as applicable, are the IHS approval authorities and signatories on DUAs permitting TEC access to IHS data.
- Once a mutually agreeable DUA draft is developed and has passed both internal IHS and TEC reviews, OPHS will circulate the final DUA in sequence to:
 - OPHS Director for signature;
 - IHS Area Director(s) for signature, as applicable.
- Unless otherwise requested by the TEC, the IHS will proceed to sign the final, negotiated DUA instrument first and before the partnering TEC.
- OPHS will deliver the final, IHS-signed DUA electronically to the requesting TEC for further routing and signature(s) to complete the fully executed DUA.
- For DUAs permitting data access for TEC(s) that focuses solely on the health of urban Indians, consultation with the IHS Areas on DUA development and inclusion of the IHS Area Director(s) as signatories on related agreements may not be performed, at IHS's discretion.

Credentialing Authorized Users

Once a TEC request is approved and a DUA established, OPHS must credential specific TEC staff as authorized IHS data recipients and users before data are received and/or accessed. Staff credentialing must be done initially for new users and requires annual renewal to maintain access to IHS data for all users. Annual credentialing renewal occurs in approximately February of each year, regardless of initial credentialing date. For example, a new user initially credentialed in November will still require renewal the following February as part of the established annual renewal cycle.

The initial staff credentialing process requires:

- Written request from the TEC Director to IHS nominating each individual staff member proposed for data access, including a brief description of each individual's TEC affiliation, organizational role, and need for access to IHS data;
 - A sample written request, which may be used as a guide, is included in Appendix E;
- Completion of trainings by nominated staff:
 - IHS Information Systems Security Awareness (ISSA) training, available at <http://www.ihs.gov/issa/>.
 - When creating an ISSA training profile, enter *Tribal Epidemiology Center* in the *Department* field.
 - The training completion certificate must be submitted to IHS, but additional email notifications generated as part of the ISSA training are for the user's records and do not need to be submitted to IHS.
 - Health Insurance Portability and Accountability Act (HIPAA) training, available at <https://www.ihs.gov/hipaa/training/>. This training is only required upon initial credentialing.
 - The training completion certificate must be submitted to IHS.
- Signed agreement with individual Rules of Behavior (Appendix F).

The annual process for renewal for existing, previously credentialed users is:

- Completion of IHS Information Systems Security Awareness (ISSA) training by individual staff, available at <http://www.ihs.gov/issa/>.
 - When creating an ISSA training profile, enter *Tribal Epidemiology Center* in the *Department* field.
 - The training completion certificate must be submitted to IHS, but additional email notifications generated as part of the ISSA training are for the user's records and do not need to be submitted to IHS.
- Signed agreement with individual Rules of Behavior (Appendix F).

Additional notes on credentialing requirements and process

- TEC staff are able to create an IHS online training account to complete trainings at www.ihs.gov, even if they have non-IHS email addresses. For assistance accessing web-based IHS training modules, please contact the IHS Office of Information Technology Service Desk at 1-888-830-7280 or itsupport@ihs.gov.
- Once all requirements are completed for all new or renewing staff, please collate and send all documentation files as pdf files *in a single package* via email to epidata@ihs.gov. Complete documentation includes:
 - Written request nominating individual staff for IHS data access (new users only)
 - Training completion certificates (as required)
 - Completed and signed individual Rules of Behavior document(s)
- Once all initial/renewal credentialing requirements are confirmed, OPHS will issue a memorandum authorizing credentialed users approved to access IHS data through an explicit expiration date, usually through the following February.

Delivery of Data to TECs

- The principal mechanism to satisfy approved TEC data requests is through the delivery of periodic data extracts generated by the IHS and shared directly with the requesting TEC.
 - Specific delivery mechanisms include distribution of data via physical media (e.g., encrypted USB drive), encrypted email transmission, or other means as technically feasible.
 - Where physical media are used, receiving TEC(s) must return media devices to IHS following specific instructions included with the device and at IHS expense to ensure sufficient media devices are available to sustain future data delivery.

V. General Timelines

OPHS will strive to observe the following timing milestones for IHS actions regarding correspondence, adjudication of requests, DUA establishment, credentialing TEC staff, and ultimate data provisioning.

Correspondence and Data Access Timing Milestones

| Activity | Milestone | Timing |
|--------------------------|--|---|
| General Correspondence | Acknowledge inquiry receipt | Immediate via auto-reply email |
| | Detailed response to general inquiries to epidata@ihs.gov | ≤5 business days of receipt |
| PHI Request Adjudication | Acknowledge request receipt | Immediate via auto-reply email |
| | Provide findings of initial administrative review of request | ≤14 calendar days of receipt |
| | Decision on request delivered to TEC | ≤30 calendar days of determining actionable request |
| DUA Establishment | Obtain IHS approvals and signatures on final DUA draft | ≤60 calendar days of mutual agreement to final DUA draft |
| Credentialing TEC Staff | Review/validate training and related documentation | ≤5 business days of receipt |
| | Issue annual approval credentialing memorandum | ≤5 business days of validating documentation |
| Data Provisioning | Build and distribute PHI to the requesting TEC | ≤30 calendar days from issuance of credentialing memorandum |