

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
TRIBAL EPIDEMIOLOGY CENTER DATA ACCESS POLICY**

SEPTEMBER 3, 2024

**SECTION 1
PURPOSE AND SCOPE**

Amendments to the Indian Health Care Improvement Act (IHCIA) in 1992 established a grant-making process to create Tribal Epidemiology Centers (TECs) in each service area of the Indian Health Service (IHS). The relevant portion of the IHCIA, 25 U.S.C. § 1621m, was further amended in 2010. This statute enumerates seven core TEC functions, which support tribal and urban Indian communities through specific types of data collection, monitoring, systems evaluation, recommendations, assistance, and disease surveillance. *See* § 1621m(b). TECs exist to advance public health in Indian country, and they are treated as public health authorities (PHAs) for purposes of the Privacy Rule promulgated under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). *See* 25 U.S.C. § 1621m(e). It is therefore critical that TECs, acting in their capacities as PHAs, have timely access to appropriate data for their public health activities.

Applicants for the TEC program are required to “demonstrate cooperation from Indian tribes or urban Indian organizations in the area to be served.” *See* 25 U.S.C. § 1621m(d)(4)(C). TECs then perform their functions “in consultation with and on the request of Indian tribes, tribal organizations, and urban Indian organizations” in their applicable area. *See* § 1621m(b). Many of the TEC functions also specifically reference the “Indian tribes, tribal organizations, and urban Indian organizations” that the TECs assist. *See* § 1621m(b)(1), (3), (6); *see* (7) for a similar reference to “urban Indian communities.” Therefore, TECs are expected to work closely with the Tribes, tribal organizations, and/or urban Indian organizations/communities in their respective area, including collaborating on data sharing and analysis, and ensuring Tribal support for data requests and projects undertaken by the TEC.

The purpose of this Tribal Epidemiology Center Data Access (TECDA) Policy is to establish a U.S. Department of Health and Human Services (HHS or Department) wide policy governing Data Access for TECs, including the scope of Data available, the process to obtain data, and the expected timelines for processing TECs’ requests for Data. It serves to establish an HHS-wide expectation for responding to requests from TECs acting in their capacities as PHAs for Data in the custody and control of HHS and its Staff and Operating Divisions (collectively referred to as “Divisions”).

By improving and clarifying how the Department will provide Data to TECs, HHS seeks to advance health equity for American Indians and Alaska Natives (AI/ANs), eliminate data disparities facing TECs, and enhance the social, physical, spiritual, economic, and health status of AI/ANs.

This TECDA Policy is applicable to all of HHS. It provides expectations and best practices for HHS to manage and respond to TEC Data requests. Divisions with Data covered by this policy shall develop or modify implementation protocols for managing and responding to TEC requests for Data administered by or held under that Division's custody and control that are consistent with this policy, including but not limited to Section 6.

SECTION 2 OBJECTIVES

- To affirm TECs' mission to support and promote public health in Indian country; and improve health services and health outcomes for AI/AN individuals, families, and communities.
- To support the work of TECs in the protection and promotion of the well-being of AI/ANs and the non-AI/AN community members they also serve.
- To advance the Administration's priorities of achieving health equity, increasing transparency, and providing support for underserved communities, *see* Executive Order 13985 on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government (Jan. 20, 2021), through the provision of Data that will enable TECs to better identify public health issues, allocate healthcare resources, and tailor actions to improve public health in Indian country.
- To address the recommendations of the U.S. Government Accountability Office in its report GAO-22-104698 (March 2022) on "Tribal Epidemiology Centers: HHS Actions Needed to Enhance Data Access."
- To establish an HHS-wide policy with respect to Data Access for TECs acting in their capacities as PHAs, while maintaining the necessary flexibility for Divisions to develop implementation protocols specific to their internal operations, data systems, applicable authorities, and existing agreements. Further specificity regarding access to and categories of Data covered by this policy shall be identified in the Division-specific protocols and guidance to be developed in accordance with this policy, as detailed in Section 5.

- To recognize HHS’s partnership with and to support the work of TECs in helping to meet the public health data needs of Tribes, Tribal organizations, and urban Indian organizations; and to support Divisions in their work to provide appropriate Data to TECs.
- To provide clear points of contact and protocols across HHS for TEC Data requests.
- To support TEC capacity building as it relates to public health activities and specifically in the context of Data Access, security, analysis, and application.
- To charge and hold HHS accountable for the implementation of this TECDA Policy.

SECTION 3 DATA AVAILABLE TO TECs

SECTION 3.1 TEC DATA AUTHORITIES, ACCESS TO PROTECTED HEALTH INFORMATION

HHS recognizes TECs shall be treated as PHAs for purposes of the HIPAA Privacy Rule, as set forth in 25 U.S.C. § 1621m(e), as amended. Data, as defined for purposes of this policy, should be disclosed to TECs upon their request for their public health activities under 25 U.S.C. § 1621m, in accordance with this policy. To the greatest extent possible, Divisions shall provide TECs with the same level of Data Access as other PHAs (e.g. state and local, agencies), without additional cost or process requirements to request or obtain data beyond what is expected of other PHAs. If TECs request protected health information (PHI) from HHS, HHS is permitted to rely on a statement from the requesting official that the requested information is the minimum necessary for the stated purpose(s), consistent with 45 C.F.R. 164.514(d)(3)(iii)(A).

SECTION 3.2 DATA PRIVACY AND SECURITY PROTECTIONS

The Department shall not provide Data to any requestor, including TECs, that cannot meet relevant privacy and security standards and requirements. Division-specific data guides shall include information about any general data security requirements related to disclosure of PHI, other personally identifiable information (PII), and other sensitive or otherwise statutorily protected data in their possession. Individual data use agreements (DUAs) between a TEC and a Division for specific Data requests shall include more detailed information about security protocols required for access. At a minimum, this shall include written assurance of Data protection to the level determined appropriate by the Division disclosing the Data, based upon the sensitivity of the Data and generally applicable standards. Individual consent for the Data to be disclosed may be required depending on the nature of the Data and applicable federal law, regulation, or agreement between HHS and third parties (e.g., “Confidentiality of Substance Use Disorder Patient Records” under 42 CFR Part 2, “Certificates of Confidentiality” under Section 301(d) of the Public Health Service

Act, , and informed consent documents.) Division-specific guides shall outline further process requirements or barriers to releasing such Data, as applicable.

SECTION 3.3 MINIMUM DATA ACCESS

In general, Divisions are expected to provide TECs the same type of existing Data that can be made available to a PHA. This includes, but is not limited to, datasets that contain Aggregate or individual-level data about their area, general datasets pertaining to public health events occurring in their area, and datasets containing information about the health, public health, and service delivery systems in their areas, consistent with Section 6.

As described below, HHS will direct Divisions to maintain lists of potentially accessible existing datasets of likely interest to TECs. HHS will not create new datasets that do not exist already and can only provide access to existing data that are under HHS stewardship.

SECTION 3.4 COMPLIANCE AND GOVERNANCE

The HHS Chief Data Officer (CDO) shall oversee the implementation of this policy in collaboration and consultation with Division CDOs and Office of Intergovernmental & External Affairs (IEA). The HHS CDO shall manage and update a public access website that facilitates access to this policy, as well as the Division-level operating protocols and guidance as described below.

SECTION 4 HHS DIVISIONS

SECTION 4.1 DIVISION PROTOCOLS AND GUIDANCE

Each Division with Data covered by this policy shall develop operating protocols and guidance for responding to Data requests from TECs that are specific to each Division's internal operations, data systems, and legal authorities. Such protocols shall ensure Data is secure and sufficiently available, consistent with this TECDA Policy. Such protocols and guidance shall ensure Data, datasets, monitoring systems, delivery systems, and other PHI in the possession of the Division is provided to the maximum extent permitted by applicable law, regulation, existing agreements, and Division privacy and security policies without the imposition of administrative conditions that are not otherwise generally applicable to PHAs.

Division protocols and guidance shall include the components necessary for efficient and effective review, evaluation, and fulfillment of TEC Data requests. Division protocols and guidance shall include at a minimum:

- 1) Procedures for submitting Data requests, including the identification of any associated documents that may be required (e.g., standard forms, templates); this shall include any additional details regarding TEC's requests for PHI, such as the minimum necessary standard under the HIPAA Privacy Rule;
- 2) Procedures for ensuring timely access by TECs to requested Data, including explicit deadlines for processing Data requests, with a maximum of 15 business days to acknowledge receipt of a request, and 90 calendar days to confirm to the TEC that the Division is in possession of the requested Data, confirm or deny whether the Division will or will not be able to provide the requested Data, and provide a description of steps necessary for the TEC to take in order to receive such Data, with these timelines contingent on the receipt of a complete Data request from the TEC;
- 3) Procedures for internal review of Data requests, including for assessing and tracking compliance with Section 6;
- 4) A list of existing potentially available datasets that are of likely interest to TECs; and
- 5) Procedures for handling denials that include issuing a written notice to the requestor with a reason for the denial.

Each Division with Data covered by this policy should consider how best to transmit responses to TEC Data requests to facilitate greater accessibility when possible and appropriate for public health activities, e.g., through machine-readable datasets, summary tables, graphs, and narratives. HIPAA-covered Divisions are encouraged to consider use of the HHS HIPAA Public Health Authority Disclosure Request Checklist as part of developing their operating protocols and guidance.¹

Each Division shall complete the requirements of this section within twelve (12) months of this policy's Effective Date.

SECTION 4.2 POINT(S) OF CONTACT

Each Division with Data covered by this policy shall designate an official point of contact or points of contact (PoCs), which may be a general inbox or inboxes and/or specified personnel position(s), for external correspondence related to TEC Data requests. The HHS Chief Data Officer shall make the master list of PoCs available on a public data access website and keep the website updated. Division CDOs will notify HHS CDO of any updates and changes impacting accuracy of information on the HHS CDO public website within 5 business days of said changes.

SECTION 5

¹ The HHS HIPAA Public Health Authority Disclosure Request Checklist is currently available at <https://aspr.hhs.gov/legal/Pages/hipaa-disclosure-checklist.aspx>.

IMPROVING DATA

SECTION 5.1 INTERAGENCY, INTERGOVERNMENTAL, AND SIMILAR AGREEMENTS

It is HHS's intent that the best practices for TEC Data Access set forth in this TECDA Policy be advanced through relevant agreements that Divisions enter into on an interagency, intergovernmental (i.e., state, Tribal, local governments), or similar basis. As applicable and feasible, Divisions are encouraged to incorporate provisions into their relevant agreements that are consistent with the purposes and objectives of this TECDA Policy (including in DUAs, grants, funding agreements, etc.) that will further adherence to these principles.

SECTION 5.2 DATA COLLECTION

Underlying this TECDA Policy, HHS acknowledges that the efficacy of Data Access and sharing rests on the foundational collection of accurate, quality data. Accurate data collection, particularly in regard to the identification of AI/AN individuals, when possible, must be an HHS-wide priority to advance the purposes of this TECDA Policy and public health investigations, actions, interventions, and health outcomes in Indian country. HHS encourages all Divisions to evaluate their internal data collection and management methodologies and data metrics as they relate to AI/AN information, including Tribal membership and multi-racial/ethnic identifying individuals.

SECTION 6 LIMITATIONS

This TECDA Policy is not intended to waive or create any Tribal governmental rights or authorities, including treaty rights, sovereign immunity, or jurisdiction. Nor does this TECDA Policy affect any rights or protections afforded to AI/AN individuals or others in regard to PHI and other PII under applicable authorities, such as HIPAA and 42 CFR Part 2 .

HHS also recognizes that the collection, management, use, analysis, disposal of, and sharing of data is subject to federal laws, policies, regulations, and, at times, by legal agreements under which data are collected that can vary by data type and dataset; therefore, careful consideration of the interplay of these laws and applicable agreements must be factored into data activities conducted in connection with the implementation of this policy. For this reason, the provision of Data and Data Access under this policy are subject to all applicable laws, existing agreements, regulations, reasonable technical constraints, and the availability of appropriations.

This policy does not supersede or modify the statutory responsibilities set forth under the United States Code that pertain to Divisions or the Secretary. Nor does it supersede or modify any other statutes, regulations, or data use or other agreements that govern HHS's or a Division's collection,

handling, disposing of, or sharing of data. In the event of a conflict between this policy and Division-specific authorities and agreements, the latter shall prevail.

Other authorities or mechanisms not covered in this policy may exist that may prohibit, prevent, or limit the disclosure of Data, such as “Confidentiality of Substance Use Disorder Patient Records” under 42 CFR Part 2, Section 301(d) of the Public Health Service Act, the Privacy Act of 1974, 5 U.S.C. 552a, and the Common Rule under 45 CFR part 46, subpart A.

In all circumstances, data shall only be provided to the extent permitted by federal law, regulation, and federal agreements in place with the underlying data source, including contracts, Certificates of Confidentiality, and notices (e.g. Privacy notices and consent agreements) with individuals from whom the data is collected.

SECTION 7 DEFINITIONS

For the purposes of this policy, terms are defined as follows:

Aggregate Data means, in general, the numerical or non-numerical information that is (1) collected from multiple sources and/or on multiple measures, variables, or individuals, and (2) compiled into de-identified data summaries or summary reports, typically for the purposes of public reporting or statistical analysis. The specific content and extent to which data is aggregated varies by dataset. Aggregate Data may be disclosed using de-identified summary statistics and other appropriate forms of data transmission and must comply with applicable data protection requirements. Where Aggregate Data cannot be de-identified in accordance with all applicable authorities, such as reportable data containing less than a threshold of a specific population needed to maintain data protections, it shall not be released except as permitted by federal law, regulation, and existing data use or other agreements.

Data means information needed for public health purposes that: is under the custody and control of HHS; can feasibly be disclosed to public health authorities for use in their public health activities pursuant to and consistent with applicable law, regulation, and existing Division agreements; and is inclusive of data included in monitoring systems, delivery systems, PHI and other PII, including, unless specified otherwise, both Tribe-specific and non-Tribe-specific information at the individual and aggregate levels relevant to that TEC’s area.

Data Access means the act of providing Data that is in HHS custody and control, including data maintained in monitoring systems and delivery systems, available for use by TECs in carrying out

their functions under 25 U.S.C. § 1621m. Direct access to monitoring systems and delivery systems may only be provided when permitted by all applicable authorities.

Department of Health and Human Services (HHS or Department) means the Cabinet-level department of the Executive branch whose mission is to enhance the health and well-being of all Americans by providing for effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services.

Division means the thirteen Operating Divisions (OpDivs) that have responsibility for administering a wide variety of health and human services and conducting life-saving research for the Nation, and the seventeen Staff Divisions (StaffDivs) that provide leadership, direction and management guidance to the Secretary and the Department. OpDivs and Staff Divs are collectively referred to as Divisions.

Health Insurance Portability and Accountability Act of 1996 (HIPAA) is a federal law that, among other things, required HHS to adopt national standards to protect the privacy and security of certain health information. The implementing rules for these standards are the HIPAA Privacy, Security, Breach Notification, and Enforcement Rules (45 CFR parts 160 and 164).

Personally Identifiable Information (PII) means information that can be used to distinguish or trace an individual's identity, either alone or when combined with other information, that is linked or linkable to a specific individual.

Protected Health Information (PHI) has the same meaning as in 45 C.F.R. § 160.103.

Public Health Authority (PHA) means an agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian Tribe, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate. *See* 45 C.F.R. § 164.501.

Secretary means the lead federal official for the U.S. Department of Health and Human Services.

Tribal Epidemiology Center (TEC) means an epidemiology center established under Section 214 of the Indian Health Care Improvement Act, as codified at 25 U.S.C. § 1621m. A list of currently funded TECs is available at <https://www.ihs.gov/epi/tecs/currently-funded-tec/>. Per 25 U.S.C. § 1621m(b), TEC functions are specified as “(1) collect data relating to, and monitor progress made toward meeting, each of the health status objectives of the Service, the Indian tribes, tribal organizations, and urban Indian organizations in the Service area; (2) evaluate existing delivery

systems, data systems, and other systems that impact the improvement of Indian health; (3) assist Indian tribes, tribal organizations, and urban Indian organizations in identifying highest-priority health status objectives and the services needed to achieve those objectives, based on epidemiological data; (4) make recommendations for the targeting of services needed by the populations served; (5) make recommendations to improve health care delivery systems for Indians and urban Indians; (6) provide requested technical assistance to Indian tribes, tribal organizations, and urban Indian organizations in the development of local health service priorities and incidence and prevalence rates of disease and other illness in the community; and (7) provide disease surveillance and assist Indian tribes, tribal organizations, and urban Indian communities to promote public health.”

Tribal Member means an individual recognized by a Tribal government as a member, citizen, enrollee, or other term signifying formal political association of that respective Tribe according to the criteria established by that Tribe.

Tribe means an Indian or Alaska Native tribe, band, nation, pueblo, village, or community that the Secretary of the Interior acknowledges to exist as an Indian Tribe pursuant to the Federally Recognized Indian Tribe List Act of 1994, 25 U.S.C. §§ 5130-31. Throughout this TECDA Policy, Tribe is used synonymously with Tribal government.

SECTION 8 EFFECTIVE DATE

This HHS Tribal Epidemiology Center Data Access Policy shall be effective immediately upon the signature of the HHS Secretary (Effective Date). There shall be a twelve (12) month implementation period, following the Effective Date, for Divisions to comply with Section 4.