U.S. Department of Health and Human Services
Tribal and Tribal Epidemiology Center Data Access Policy

Section 1
Purpose and Scope

Tribal sovereignty was recognized by the United States in the U.S. Constitution in 1787, establishing the political relationship that continues to exist between the federal government and each federally recognized Tribe (Tribe). This government-to-government relationship has been given form and substance by numerous treaties, laws, federal judicial precedent, and Executive Orders. It reaffirms the right of Tribes to self-determination and self-governance over their members, territory, and resources.

Tribal sovereignty serves as the Tribal governments' basis to exercise authority over public health matters impacting their Tribal Members, as well as emerging threats and other health-related needs in their communities. Agencies and authorities of a Tribe responsible for public health matters as part of their official mandate, as well as those acting under a grant of authority from or contract with that public health agency, are public health authorities (PHAs) for purposes of the Privacy Rule promulgated under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Tribal Epidemiology Centers (TECs) also serve to advance public health in Indian country, and they are treated as PHAs for purposes of HIPAA pursuant to the Indian Health Care Improvement Act (IHCIA), 25 U.S.C. § 1621m€. It is therefore critical that Tribes and TECs, acting in their capacities as PHAs, have timely access to appropriate data for their public health activities.

The purpose of this Tribal and Tribal Epidemiology Center Data Access (TTDA) Policy is to establish a U.S. Department of Health and Human Services (HHS) wide policy for outlining the types of Data to be made available to Tribes and TECs, acting in their capacities as PHAs. It also serves to establish an HHS-wide expectation for responding to requests from Tribes and 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").

The goals of this TTDA Policy include, but are not limited to, advancing health equity for American Indians and Alaska Natives (AI/ANs), eliminating data disparities and inequities facing Tribes, TECs, and PHAs created by or serving Tribes, ensuring Tribal Data access is maximized to the extent permissible under federal law, regulation, and existing agreements, and advancing or enhancing the social, physical, spiritual, economic, and health status of AI/ANs.

This TTDA Policy is applicable to all of HHS. It provides expectations and best practices for HHS to manage and respond to Tribal and TEC Data requests, to the extent permitted by federal law, regulation, and federal agreements in place with underlying data sources. Divisions with Data covered by this policy shall develop implementation protocols for managing and responding to Tribe and TEC requests for data administered by or held under that Division's custody and control that are consistent with this policy, to the extent permitted by applicable authorities and agreements.

This TTDA Policy is not intended to waive any Tribal governmental rights or authorities, including in treaty rights, sovereign immunity, or jurisdiction. Nor does this TTDA Policy affect any rights or protections afforded to AI/ANs or others in regard to protected health information (PHI) and other personally identifiable information (PII) under HIPAA and other applicable authorities.

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.

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.

SECTION 2
OBJECTIVES

- To affirm Tribal sovereignty to support and promote public health in Indian country; increase visibility of AI/ANs in health data; provide culturally credible and relevant data for Tribal health decision-making; and improve health services and health outcomes for AI/AN individuals, families, and communities;

- To facilitate Tribal input on the use of Tribe-Specific Data, when feasible or as appropriate.

- To support the work of Tribally created PHAs and TECs in the protection and promotion of the well-being of AI/ANs and the non-AI/AN community members Tribes 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 reduced barriers to Data access that will enable Tribes 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 Tribal Data access and Data Sharing with Tribes and TECs acting in their capacities as PHAs, to the extent feasible and permitted by federal law, regulation, and any existing agreements in place between HHS and third parties, while maintaining the necessary flexibility for Divisions to develop implementation protocols specific to their internal operations and data systems with Tribal sovereignty considerations. 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 the partnership and 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 the extent feasible and permitted by federal law, regulation, and any existing agreements in place between HHS and third parties, to TECs acting in their capacities as PHAs.

- To provide clear points of contact and transparency at HHS in relation to Tribal and TEC Data requests.

- To support Tribe and 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 TTDA Policy.

[POLICY CONTINUED ON NEXT PAGE]

SECTION 3
DATA AVAILABLE TO TRIBES AND TECS

SECTION 3.1 TRIBAL PUBLIC HEALTH AUTHORITY DATA

Upon request by a PHA created by a Tribe, Data, as defined for purposes of this policy, should be disclosed to that PHA for public health purposes to the extent feasible and permitted by applicable legal authorities and existing agreements. Tribally created PHAs seeking access to Data protected by HIPAA should provide a minimum necessary representation, consistent with 45 C.F.R. 164.514(d)(3)(iii)(A). Further specificity regarding access to and categories of Data shall be identified in the Division-specific protocols and guidance to be developed in accordance with this policy, as detailed below. Other authorities or mechanisms not covered in this policy may exist that may prevent or limit the disclosure of Data. Tribe-Specific Data, including in the aggregate, under the custody and control of a Division are subject to additional provisions set forth in this TTDA Policy.

SECTION 3.2 TEC PUBLIC HEALTH AUTHORITY DATA

HHS recognizes TECs shall be treated as PHAs for purposes of HIPAA, 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, to the extent feasible and permitted by federal law, regulation, and existing agreements. TECs seeking access to Data protected by HIPAA should provide a minimum necessary representation, consistent with 45 C.F.R. 164.514(d)(3)(iii)(A). As more fully described in Section 4, Divisions may receive an opt-out request from a Tribe for Tribe-Specific Data disclosures to a TEC. Such opt-out requests will be used to inform the minimum necessary data for the TEC's public health activities. Other authorities or mechanisms not covered in this policy may exist when the Data cannot be disclosed to the TEC or a Tribe as a PHA.

SECTION 3.3 DEIDENTIFIED AGGREGATE DATA

When deidentified in accordance with all applicable authorities, Tribes and TECs acting in their capacities as PHAs shall have access, upon their request, to Aggregate Data for AI/AN individuals, populations, geographies, or for other populations, to the extent feasible and permitted by federal law, regulation, and existing agreements. Aggregate Data may be disclosed using deidentified summary statistics and other appropriate forms of data transmission and must comply with data protection requirements. Where Aggregate Data cannot be deidentified in accordance with all applicable authorities, such as the reportable data containing less than a threshold of a specific population needed to maintain data protections, then it shall not be released except as permitted by federal law, regulation, and existing data use or other agreements.

SECTION 3.4 INDIVIDUAL DATA PROTECTIONS

In keeping with the concept of protecting individual rights under HIPAA and other applicable authorities, as well as the spirit of privacy laws generally, Divisions shall include specific procedures for addressing the security of Data disclosed to Tribes and TECs acting in their capacities as PHAs. 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. Consent or reason for the Data request may be required depending on the nature of the Data and applicable federal law or regulation, such as 42 CFR Part 2, Section 301(d) of the Public Health Service Act, and the HIPAA Privacy Rule. Division-specific policies shall outline further requirements or barriers to releasing such Data, as applicable.

SECTION 3.5 SHARE BACK PROVISION

All public health data submitted by a Tribe or TEC into or for a Division dataset or data system is considered Data covered by this policy. When a Tribe or TEC requests access to the Data it submits to a Division for public health activities, and to the extent feasible and permitted by federal law, regulation, and existing agreements, every effort should be made to share back those Data submitted directly by the Tribe or TEC in a timely manner by the recipient Division.

SECTION 4
TRIBAL OPT-OUT OF DATA DISCLOSURES TO TECS

It is the policy of HHS that data about AI/ANs in the custody and control of a Division should be disclosed to TECs, upon their request, for their public health activities under 25 U.S.C. § 1621m, to the extent feasible and permitted by federal law, regulation, and existing agreements. While TECs are intended to assist Tribes with addressing and improving Tribal public health, HHS acknowledges that Tribes may elect not to work with their Area's TEC and may also have concerns about disclosure of Tribe-Specific Data to that TEC. To take into consideration a Tribe's particular concerns about disclosure of Tribe-Specific Data to TECs, Divisions shall include specific procedures for receiving and addressing Tribal opt-out requests in their Division-specific protocols and guidance developed pursuant to this policy.

Consistent with the HIPAA Privacy Rule, Divisions may reasonably rely on a minimum necessary representation made by the TEC in requesting PHI. However, if the Division receives a Tribal opt-out request, the Division shall consider whether that request informs a different determination of the minimum necessary data for the TEC's public health activities. Depending on the Data requested and the applicable authorities, Divisions may use or rely on other standards or determinations in releasing the Data. The Divisions should consider Tribal opt-out requests to the greatest extent possible, when assessing those other standards or determinations. Divisions shall use best efforts and explore their capability to isolate and extract the Tribe-Specific Data in

anticipation of opt-out requests. Even with an opt-out in effect, a Tribe's data may still be disclosed to TECs in deidentified, aggregate forms for various purposes under applicable law.

SECTION 5
HHS DIVISIONS

SECTION 5.1 DIVISION PROTOCOLS AND GUIDANCE

Each Division with Data covered by this policy shall develop operating protocols and guidance for responding to Data requests from Tribally created PHAs and TECs that are specific to each Division's internal operations and data systems. Such protocols shall ensure Data is secure and sufficiently available, subject to applicable law and regulation, as well as existing agreements, and consistent with this TTDA Policy. Such protocols and guidance shall ensure access to Data, datasets, monitoring systems, evaluation systems, and delivery systems is facilitated to the maximum extent permitted by applicable law, regulation, and existing agreements without the imposition of restrictive administrative conditions that are not otherwise generally applicable to PHAs.

Division protocols and guidance shall include, at a minimum, procedures for submitting Data requests, timelines for processing Data requests, internal review procedures, the identification of any associated documents that may be required (e.g., standard forms, templates), procedures for ensuring timely access by Tribally created PHAs and TECs to Data, and other components necessary for efficient and effective review, implementation, and evaluation of actions as public health activities. Each Division with Data covered by this policy should consider how best to transmit responses to Tribal and 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. 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]

Consistent with the HHS and Division-specific Tribal Consultation Policies, Divisions shall develop their respective operating protocols and guidance in consultation with Tribes. Divisions shall undertake to complete the requirements of this section within eighteen (18) months of this policy's Effective Date.

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

SECTION 5.2 POINT(S) OF CONTACT

Each Division with Data covered by this policy shall designate an official point of contact or points of contact, which may be a general inbox or inboxes and/or specified personnel position(s), for external correspondence related to Tribe and TEC Data requests. The point(s) of contact shall also help coordinate the tracking and management of Tribal opt-out requests regarding TEC disclosures within the Division and in collaboration with the relevant Tribe or Tribes.

SECTION 5.3 PERIODIC TRIBAL INPUT

Each Division with Data covered by this policy shall periodically solicit feedback and input from Tribes and TECs on Data Sharing, which may include but not be limited to issues such as the efficacy and efficiency of their respective operating protocols and guidance, as well as gaps in data practices, collection, and reporting methods as they relate to Tribal data. Such periodic feedback process shall seek to identify any gaps in Data Sharing practices and reporting methods as they relate to Tribal data. Divisions are encouraged to engage with Tribes and TECs early and throughout the process to receive input on data access and delivery related issues through listening sessions, formal consultation, and/or other means.

SECTION 5.4 FEDERAL EMPLOYEE TRAINING

Training on this TTDA Policy shall be annually required of all HHS management staff and of any employees and contractors working directly with Tribes and/or TECs on data sharing efforts beginning within one year of the establishment of this policy. Training will be developed by HHS, offered through the Learning Management System, and may be incorporated into broader training initiatives around Tribal sovereignty and self-governance or HHS data sharing practices more generally.

SECTION 5.5 INTERAGENCY, INTERGOVERNMENTAL, AND SIMILAR AGREEMENTS

It is HHS intent that the best practices for Tribe and TEC Data access set forth in this TTDA 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 should incorporate provisions into their relevant agreements that are consistent with the purposes and objectives of this TTDA Policy (including in data sharing agreements, grants, funding agreements, etc.) that will further adherence to these principles. HHS shall also provide template language to help further these goals.

SECTION 5.6 DATA GOVERNANCE BOARDS AND ADVISORY BODIES

To the extent possible, Divisions are encouraged to solicit the participation of elected Tribal officials and Tribal subject matter experts on federal-public data governance boards and other data

advisory bodies, if permitted by applicable law. Where none exist, Divisions may consider establishing such advisory bodies, including Tribal specific data advisory bodies, where permitted in accordance with applicable law. Divisions are also encouraged to solicit input on data related matters through their respective Tribal advisory committees, as applicable.

SECTION 5.7 DATA COLLECTION

Underlying this TTDA Policy, HHS acknowledges that the efficacy of Data access and sharing rests on the foundational collection of accurate, quality data. Accurate Tribal data collection, particularly in regard to the identification of AI/AN individuals, must be an HHS-wide priority to advance the purposes of this TTDA 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. Divisions with Data covered by this policy should engage with Tribes in this data collection practices evaluation through listening sessions and/or formal consultation.

SECTION 6
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 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.

Data means information, including biological, gene-sequenced, genomic, paleogenomic, and behavioral and social sciences data, under the custody and control of HHS that can feasibly be disclosed to public health authorities for use in their public health activities pursuant to applicable law, regulation, and existing Division agreements, and that is inclusive of monitoring systems, delivery systems, PHI and other PII, including, unless specified otherwise, both Tribal and non-Tribal information.

Data Sharing means the act of making data in HHS custody and control, including data systems and data sets, available for use by Tribes and TECs in their capacities as public health authorities and subject to applicable laws, existing agreements, regulations, reasonable technical constraints, and the availability of appropriations.

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 twelve 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 nineteen 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 required the creation of national standards to protect sensitive patient health information from being disclosed without the patient's consent or knowledge. HHS issued the HIPAA Privacy Rule to implement the requirements of the law. The complementary HIPAA Security Rule protects a subset of primarily electronic information covered by the Privacy Rule.

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 CFR § 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/.

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 TTDA Policy, Tribe is used synonymously with Tribal government.

Tribe-Specific Data means Data pertaining to a specific Tribe or concerning a specific Tribe's Members, to the extent that: (1) such data is identifiable within the dataset, (2) it is being disclosed with attribution to that specific Tribe, and (3) it is feasible to segregate that portion of the Data. When those three criteria are met, examples of Tribe-Specific Data would include:

- Data that specifically pertains to a specific Tribe via geographic data collection area
- Data submitted by a single Tribe or collected by or on behalf of a single Tribe
- Data that identifies Tribe membership or affiliation, including self-identification

Data pertaining to a specific Tribe or concerning Tribal Members is not considered Tribe-Specific Data for the purposes of this policy when data is not identifiable or attributable to a single Tribe (for example, if the data is only being presented in aggregate form that does not reference a specific Tribe or Tribes, or when the data is not being disclosed). Division-specific protocols and guidance developed in accordance with this policy shall further define the scope of Tribe-Specific Data with consideration of their data systems and datasets.

SECTION 7
EFFECTIVE DATE

This HHS Tribal and Tribal Epidemiology Center Data Access Policy shall be effective immediately upon the signature of the HHS Secretary. There shall be an eighteen (18) month implementation period for Divisions to comply with Section 5.