



HOW TO COLLABORATE WITH LAWYERS & OTHER PARTNERS ON DATA USE AGREEMENTS

An Introduction for Public Health Program Managers



THE PUBLIC HEALTH LAW CENTER



LAND ACKNOWLEDGMENT





based on work for First Nations Health Authority at Gathering Wisdom VI Drawing
change

Image credit: Sam Bradd <https://drawingchange.com/gathering-wisdom-visuals-for-a-healthy-future/>

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-  Legal Research
-  Policy Development, Implementation, Defense
-  Publications
-  Trainings
-  Direct Representation
-  Lobby

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COLLABORATION WITH THE COUNCIL OF STATE AND TERRITORIAL EPIDEMIOLOGISTS (CSTE)



- Providing legal and policy research
- Developing resources
- Conducting trainings



- Conducting an assessment of barriers to data sharing
- Preparing resource repository
- Sharing resources with their members

TODAY'S AGENDA

- Recurrent themes in public health data sharing
- Overview of relevant laws
- Case study: North Carolina DHHS data framework
- Additional tips and resources
- Q & A

“What are the pain points when it comes to public health data sharing?”

PAIN POINT THEMES:

- 1. Too many layers** of internal review and approval

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1. **Too many layers** of internal review and approval
2. **Legal review slows things down**, whether the agreement involves the health department only or the health department and other parties
3. Legal and leadership **may not understand** public health data sharing generally
4. Public health staff do not always understand the **reasons for and scope of DUAs**

POLL: WHICH OF THESE IS YOUR BIGGEST ISSUE?

- Too many layers of internal review and approval
- Legal review is very slow
- Legal and leadership do not understand public health data sharing
- PH staff do not understand the reasons for and scope of DUAs
- Other (Please put the issue in the chat)

ELEMENTS OF DATA GOVERNANCE

WHAT IS IT?

- "Is it Legal?"
- Legal is one piece of the puzzle
- “Data governance is the people, policies, and procedures that support how data are used and protected.” ([AISP resource](#))



ELEMENTS OF DATA GOVERNANCE

WHAT IS IT?

- Involves multiple parties and/or roles
- Multidisciplinary team
 - Data owner
 - Data stewards
 - Data custodian
 - Attorney
 - Privacy Officer
 - Security Officer
 - Other



WHAT ARE ATTORNEYS LOOKING AT WHEN THEY REVIEW DATA USE AGREEMENTS?

- Relevant state and federal laws
- How those laws apply to your use case
- Assess risk of potential legal issues
- Ensure that project complies with relevant law



ADDITIONAL CONSIDERATIONS



- Support data use that leads to community health benefits
- Help agency staff understand the law

LEGAL FRAMEWORK FOR PUBLIC HEALTH DATA SHARING

THE LAW

- What laws apply?
 - HIPAA
 - 42 CFR 2
 - Common Rule
 - State privacy laws



THE LAW: HEALTH INSURANCE PORTABILITY & ACCOUNTABILITY ACT (HIPAA)

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- Applies to "covered entities"
- Covered entities may designate themselves as hybrid entities



THE LAW: A BASIC HIPAA ANALYSIS

Does HIPAA apply to your program area?



THE LAW: A BASIC HIPAA ANALYSIS

If HIPAA does apply, then...

- Is deidentified information sufficient?
 - Is a limited data set sufficient?
 - Does an exception apply?
 - Is authorization required for the use or disclosure?

THE LAW: HIPAA'S PUBLIC HEALTH EXCEPTION

- Allows a covered entity to use or disclose PHI to a public health authority
- Minimum necessary rule
- Covered entity may rely on PHA's assessment of minimum necessary



THE LAW: HIPAA'S PUBLIC HEALTH EXCEPTION

Public Health Authority

An agency or authority of the US, a State, political subdivision of a State, or an Indian Tribe that is responsible for public health matters as part of its official mandate.



THE LAW: HIPAA'S PUBLIC HEALTH EXCEPTION

Minimum Necessary

Applies to uses and disclosures of PHI
for PH purposes

Allows a covered entity to rely on the PH
authority's requested disclosure as
minimum necessary



THE LAW: HIPAA'S PREEMPTION STANDARD

What law applies?

General rule: HIPAA controls
over contrary state law



EXCEPTIONS TO HIPAA'S PREEMPTION STANDARD

If state law provides greater privacy protections, state law controls

If state law provides for reporting of certain public health-related information

THE LAW: 42 CFR PART 2

- Protects confidentiality substance use disorder (SUD) records
 - But only for *Part 2 Programs*
- ***"The regulations in this part . . . are intended to ensure a patient receiving treatment for [SUD] . . . is not made more vulnerable by reason of the availability of their record than an individual with a [SUD] who does not seek treatment."*** 42 CFR 2.2(b)(2).

THE LAW: 42 CFR PART 2 FINAL RULE

- Allows single consent for future treatment, payment and healthcare operations (TPO) uses and disclosures
- Broadens description of recipient in Part 2 consent
- Better aligns elements of consent and notice of privacy practices with HIPAA
- Deidentified data may be shared with public health authorities
- Adopts HIPAA's breach notification rule

THE COMMON RULE

A federal law that provides protections for human research subjects.



EXAMPLE: PH SURVEILLANCE VS. RESEARCH

Research

NIH funds a study aimed at addressing the magnitude of tobacco use among families with small children in rural communities, but the University Principal Investigator (PI) collects additional information regarding health status to study the impact of secondhand smoke in children.

Public Health Surveillance

NIH funds the collection of data by a University PI to assess the prevalence of tobacco use among families with small children in rural communities. The purpose of the study is to identify the magnitude of tobacco use among this population and assist NIH in developing proper control measures.

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STATE PRIVACY LAWS

Protect certain types of information:

- HIV
- Immunization Registry Information
- Communicable Disease
- Behavioral health



POLL: HOW FAMILIAR ARE YOU WITH THE LAWS IN YOUR JURISDICTION THAT GOVERN DATA SHARING?

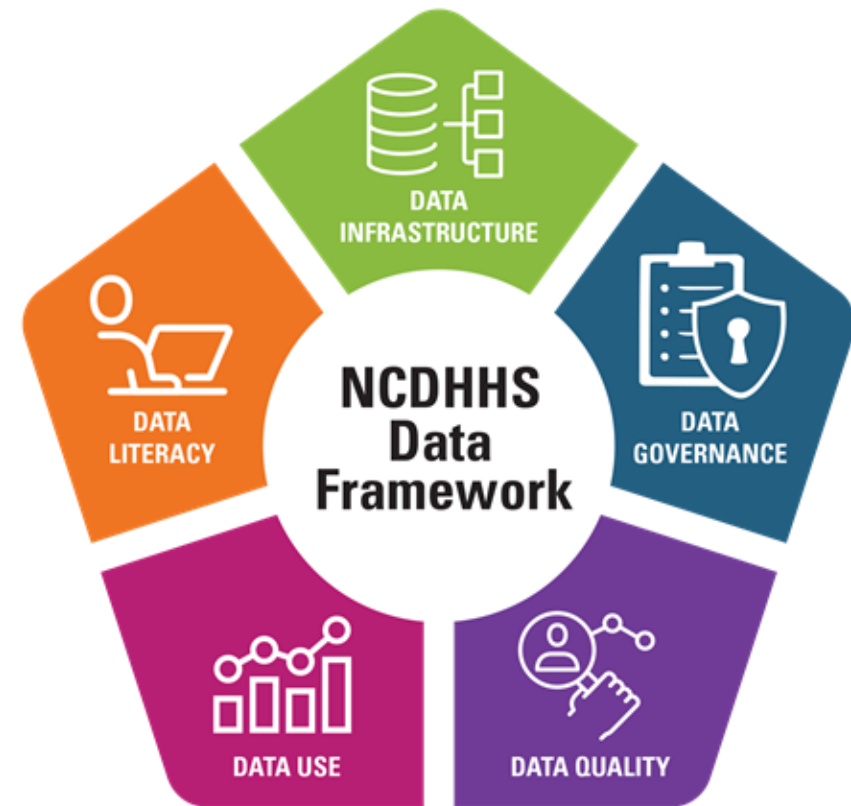
- Very familiar
- Somewhat familiar
- Not very familiar
- These issues are completely new to me

CASE STUDY:

NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES DATA FRAMEWORK

THE DATA FRAMEWORK

- Established the NCDHHS Data Office in 2019 to drive Department-wide **cultural transformation in data** collection, governance, and use
- Data as strategic business asset
- Data strategy and roadmap based on 5 data pillars
- Vision executed in partnership with technology, legal, privacy/security, Division, and Program teams



DATA GOVERNANCE – KEY EFFORTS

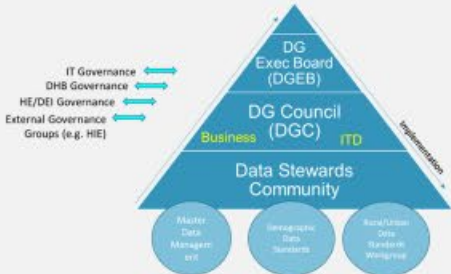
Data Stewardship

Data Sharing

Metadata & Data Classification

Data Standards

DHHS Data Gov. Organization

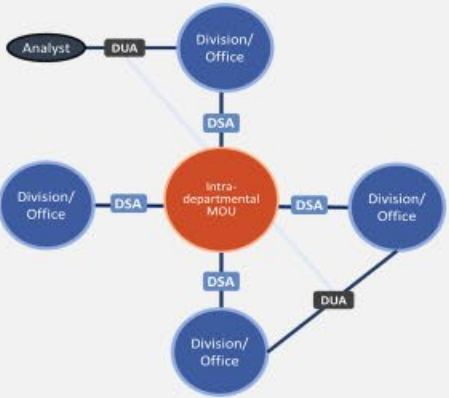


Data Sharing Guidebook



Data Sharing Guidebook

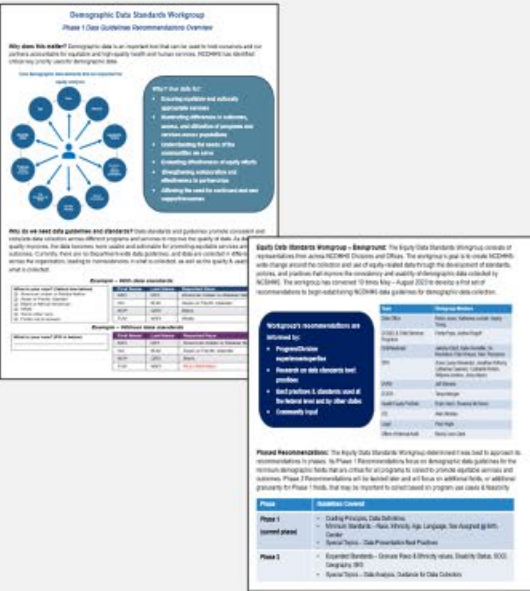
Legal Framework



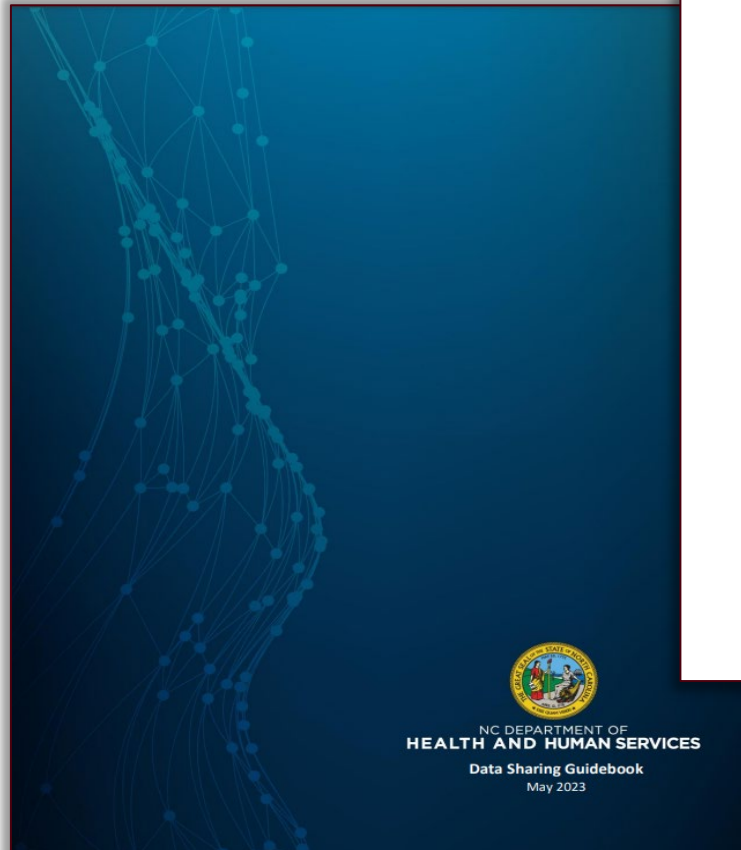
Data Asset Inventory



Demographic Data Standards



DATA SHARING – DATA SHARING GUIDEBOOK (DSGB)



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5/26/23

NCDHHS Data Sharing Guidebook

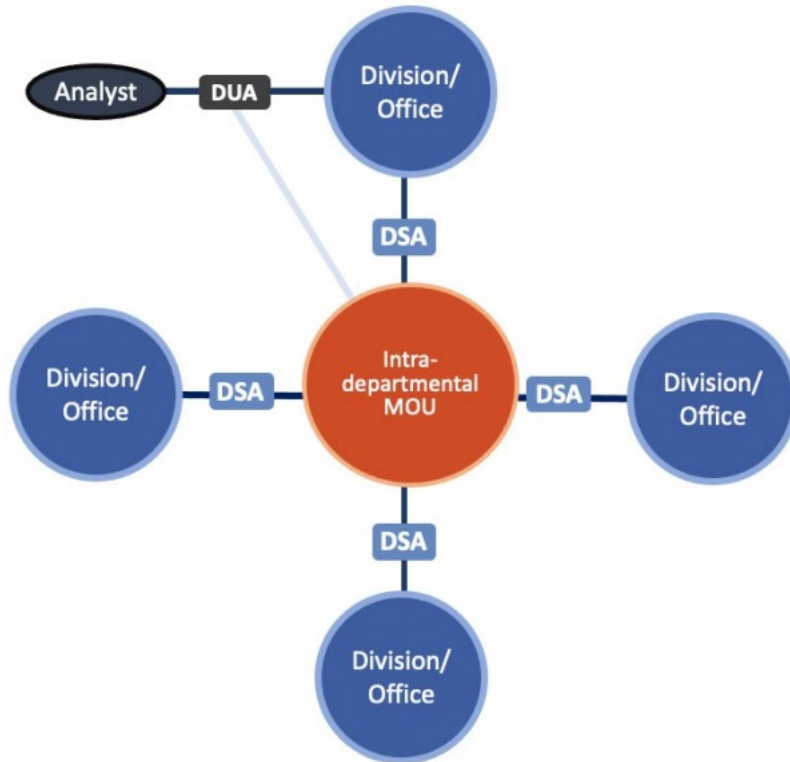
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How to use the DSGB:

- To understand the basics of how DHHS does data sharing
- To understand different roles in the data request process
- To understand steps to follow to request or share data from multiple pathways (e.g., operational vs. research request) and angles (e.g., multiple Divisions, single Division, etc.)
- Specific data sharing topics – data deidentification, data transfer, data storage

Data Sharing Guidebook

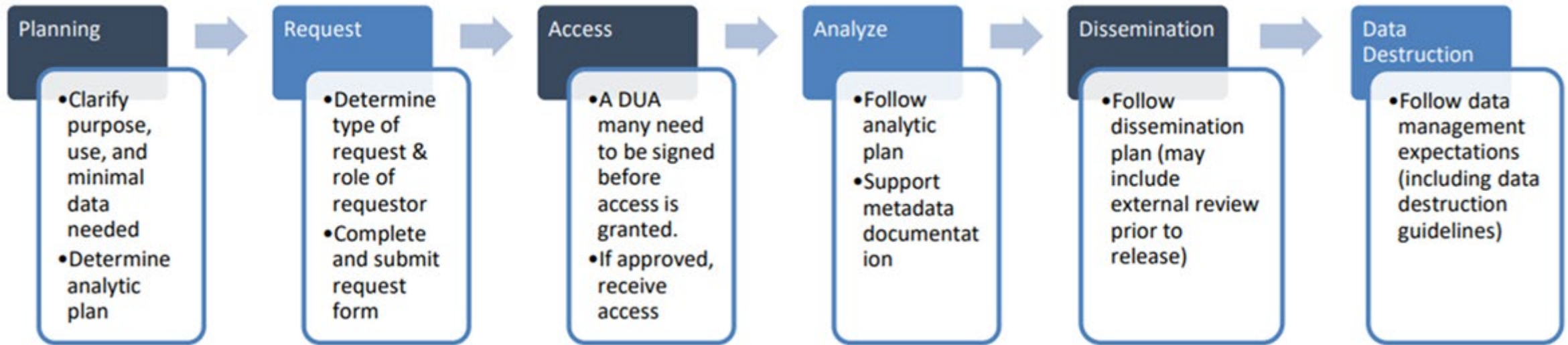
DATA SHARING – LEGAL FRAMEWORK



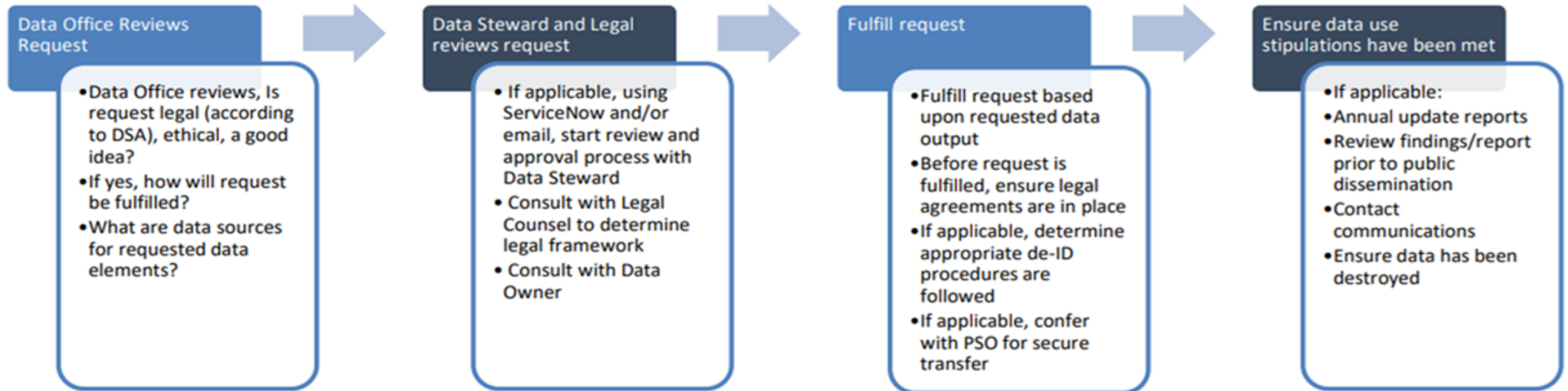
FOUNDATIONAL LEGAL AGREEMENTS

LEGAL DOCUMENT	PURPOSE	PROCESS	SIGNATORY
<u>Intradepartmental MOU</u> <i>Overarching process and guiding principles document signed by all Divisions / Offices</i>	The <u>IMOU</u> documents the purpose and governance process. The IMOU will be signed by all data partners as they enter the collaboration. The IMOU references the data sharing agreements, data use agreements, policies, and procedures for data access and use (e.g., NCDHHS Data Sharing Guidebook).	Drafted by Data Office, reviewed by legal counsel, signed by Executive Leadership and updated through the NCDHHS Data Governance Council as needed.	All Division and Office Directors and Secretary's Office are parties to 1 agreement
<u>Data Sharing Agreement</u> <i>Division / Office Specific</i>	The <u>DSA</u> includes the specific terms and conditions that govern how division- and office-specific data are transferred, stored, and managed when shared and integrated across the Department. The DSA references and reinforces the IMOU and the DUA. This document is specific to Division and Office held data.	Drafted by Data Office and Division/Office specific legal counsel. Reviewed and updated annually, or as agreed upon.	1 DSA per Division/Office Signed by Division and Office Director, the Data Office, and Information Technology Division
<u>Data Use Agreement</u> <i>Data Request Specific</i>	Legal counsel determines if a <u>DUA</u> is needed for a specific request. The DUA outlines the role and responsibilities of the data recipient. If applicable, this document is attached to the Data Request Form, which includes relevant fields, depending on the request, including: purpose, data fields, anonymization procedures, dissemination plan, and timeline of project completion. A DUA must be executed prior to data access.	Data request is identified by type and reviewed appropriately based upon the type of request. Legal counsel determines if a DUA is applicable. If yes and request is approved, a DUA is executed.	DUAs are used as needed for use cases not covered by DSAs. Signed by Data Recipient and Data Owners (if applicable)

Data Request Process for Requestors



Data Request Process for Receiving and Processing a Request



IMPACT TO NCDHHS

- ✓ Fostered a positive data culture by:
 - Building trust in and access to our key data assets
 - Encouraging collaboration across NCDHHS programs and strategic partners
 - Promoting a data-centric mindset across our organization
- ✓ Clarified roles, responsibilities, processes, and policies to enable more streamlined and efficient data sharing
- ✓ Provided a robust data support foundation to strengthen data partnerships, manage technical implementation activities, improve coordination, and expand data capacity
- ✓ Enabled mission-critical key initiatives that improved service delivery and outcomes, while maintaining and strengthening privacy safeguards and legal requirements

ROLE OF LEGAL COUNSEL IN DATA REQUESTS

- ✓ Researching, monitoring, advising on, and supporting implementation of changes in the law that impact data access and use
- ✓ Drafting and maintaining template agreements
- ✓ Reviewing and negotiating agreements
- ✓ Reviewing data requests to determine what is permitted in specific use cases
- ✓ Supporting privacy and security officers in assessing risks and responding to security incidents and breaches

How can you help your legal counsel?

- **Engage early**
- **Be prepared, transparent, and responsive**
- **Assume good intent**

DATA REQUESTS – TIPS

- Connect with data owners and stewards to understand what is available and feasible and understand the limitations of the data.
- Reach out to legal counsel early, with plenty of time for legal review and to put any necessary agreements in place.
- Prepare and provide documentation regarding the request, which may include:
 - Description of the use case
 - Requested data source and data output (requested fields; line level v. aggregated; identified v. de-identified; linked/integrated with other sources)
 - Data flow, if multiple partners are involved or there will be downstream sharing
 - IRB protocol and approval (if applicable)
- Use plain language to explain the request.
- Limit requests for confidential data to the minimum necessary for the use case.
- Become familiar with the legal frameworks that apply.

WRAP UP: TIPS AND RESOURCES

QUESTION



- What strategies have helped you develop a productive working relationship with your attorney?
- Please put your answer in the chat.

ARE MY CONVERSATIONS WITH MY ATTORNEY CONFIDENTIAL?

- Generally, conversations between a client and their attorney are confidential.
- Talk to your attorney about how to preserve attorney-client privilege.



TRIBAL RESOURCES

[Tribal Data Sharing Agreement Checklist for Use by State and Tribal Nations and Model Tribal Data Sharing Agreement.](#) Prepared by the [American Indian Health Commission for Washington State](#)

[Factsheet: Data Governance Strategies for States and Tribal Nations.](#) Prepared by the [Network for Public Health Law](#))

[Enhancing Data Access to Improve American Indian and Alaska Native Health: A Framework for State and Local Public Health Officials.](#) Prepared by the [Council of State and Territorial Epidemiologists](#)

[U.S. Gov't Accountability Off., GAO 22-101498, *Tribal Epidemiology Centers HHS Actions Needed to Enhance Data Access* \(2022\)](#)

ORGANIZATIONS THAT PROVIDE SUPPORT

- [Public Health Law Center](#)
- [Network for Public Health Law](#)
- [ChangeLab Solutions](#)
- [Association of State and Territorial Health Officials](#)
- [Council for State and Territorial Epidemiologists](#)



GENERAL RESOURCES

- [Tips for Working with Your Attorney on Public Health Data Sharing Agreements](#)
- [CSTE, Basic Principles of Privacy Risk in Public Health](#) (online course)
- [Network for Public Health Law's Webpage on Data Sharing](#)
- [Pathways to Yes, Network for Public Health Law and Data Across Sectors for Health](#) and [Webinar about Pathways to Yes](#)
- [Data Sharing 101 | Public Health Law Center](#)
- [North Carolina Department of Health and Human Services Data Sharing Guidebook](#)
- [Finding a Way Forward: How to Create a Strong Legal Framework for Data Integration](#)

Q AND A



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FUNDING STATEMENT

This webinar was supported by the Centers for Disease Control and Prevention of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award totaling \$949,000 with 100 percent funded by CDC/HHS. The contents are those of the authors and do not necessarily represent the official views of, nor an endorsement, by CDC/HHS, or the U.S. Government.