Data Usage Agreements (DUAs)

What are DUAs?

A **Data Usage Agreement** (DUA) is a contractual document used for the transfer of research data between two entities or organizations, and where the data is nonpublic or is otherwise subject to some restrictions on its use (e.g., HIPAA).

Any such agreement must be signed by the outside institution or company and an **Ohio State designee** who has signature authority to bind Ohio State to the terms.

When are DUAs used?

If an Ohio State researcher wants to transfer any health information (identifiable, de-identified and coded-limited), with another institution or company. The Office of Innovation and Economic Development (formerly "TCO") and the Office of Sponsored Programs (OSP), individually and collaboratively with other departments, review DUAs for research purposes.

When sharing data with a company, additional terms, fees, and conditions may be required in different circumstances by the company or Ohio State.

What do DUAs contain?

- At a minimum, any DUA must contain provisions that address the following:
    - Establish the permitted uses and transfer methods of data.
    - Detail the **data types** being used (i.e., PHI, de-identified, coded limited) and **list the data elements** of clinical health information being transferred.
    - Identify the roles on the study team that may use or receive the information.
    - Prohibit the recipient from using or **further sharing** data, except as permitted by the agreement or as otherwise permitted by law.
    - Include the appropriate **safeguards** to prevent unauthorized use or disclosure not contemplated by the agreement.
    - Prohibit the recipient from **identifying** the information or **contacting** individuals.

DUA Tip Sheet

Note: *The review process for agreements can take several weeks to months for all parties involved to agree on the final terms. To ensure a smooth process, it is important to collect the necessary documents, previous agreements, and information related to the data transfer in advance of agreement submissions.*

Submission Process:

- Investigators and staff may **upload** the DUA to the Office of Innovation and Economic Development (formerly "TCO") website for review. Choose the 'DUA Request Forms' hyperlink. See the **Signature Routing Chart** on page 3.
- Within the form, provide the name(s), contact information, and addresses of the outside principal investigator or company contact and the Ohio State principal investigator.
- Describe the **types of data** that will be shared (de-identified, coded-limited, or PHI with IRB approval) and the **transfer method** (e.g., encrypted email). See Email Security and Encryption.
- If applicable, mention the following:
    - Whether the study is **IRB-approved**. The protocol should include a **detailed description** of the research purpose, data types, funding and grant details, description of the transfer process, names of the other parties receiving/sending data, the name and purpose of software or platforms involved, and data access permissions (e.g., who can view protected health information (PHI).
    - Provide only the data **reflected** within the protocol. See Minimum Necessary Requirement.
    - Detail the data transfer process and the individuals involved.
    - A list of all the **participating institutions**, organizations, commercial entities, and third parties that will be involved in the transfer process and/or research conducted.
    - Mention who should have **access** to the data, particularly PHI, and for how long.
- State whether there are any **previously executed** agreements associated with the study or other parties involved.
    - Also, inform OEID if an Ohio State department (e.g., OSP, Purchasing) has **previously negotiated fees** or any part of the agreement before it is submitted for legal review.
    - The agreements may be overarching study agreements or preparatory to the collaboration (e.g., Statement of Work, Master Services Agreement, Memorandum of Understanding, Non-disclosure Agreement, and approved budgets).
- Share the **unsigned version** for review if another party created the draft DUA. Otherwise, OIED will draft a new agreement to be used.
- Agreements are not active until **both parties** have signed and agreed upon all final terms.
    - Provide the name and contact information for the Ohio State representative who handled the negotiations.

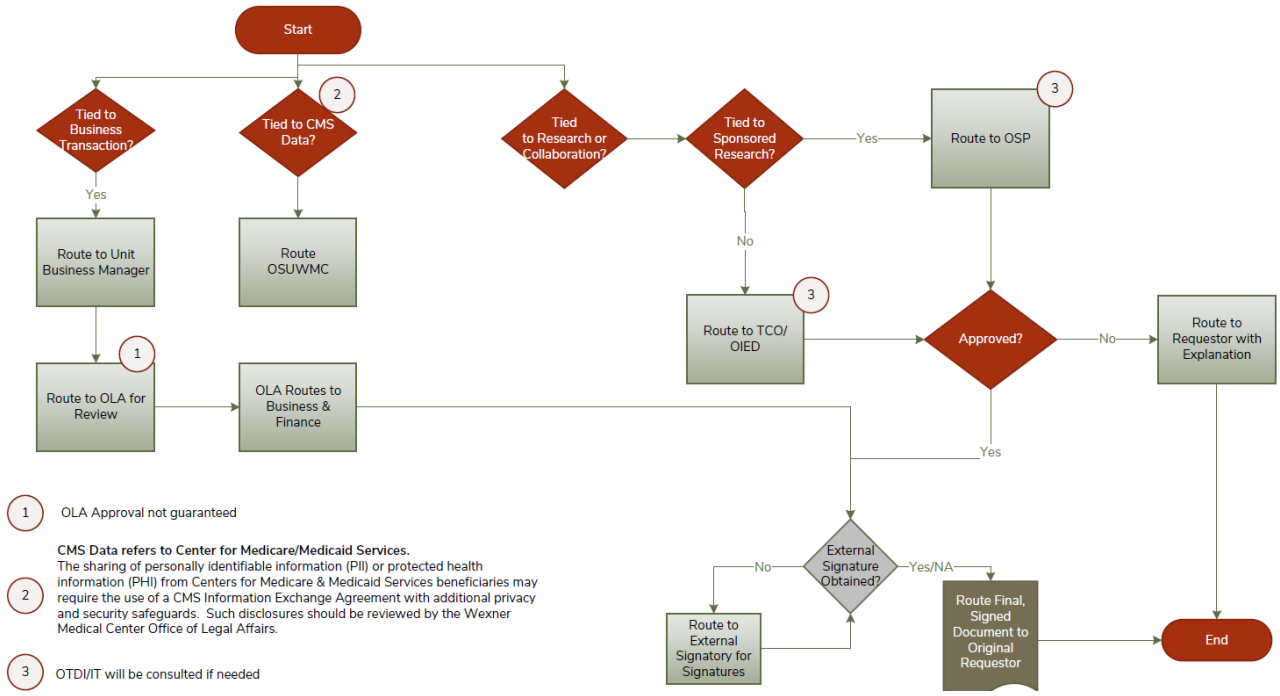
Agreement Review:

- Before data can be transferred, the DUA must be signed by **authorized signatories** from the Ohio State legal offices, the Medical Center, or the university.
    - Agreements may also have a line for Ohio State principal investigators to sign, but this is optional.
- Each agreement is unique, therefore **processing time** can vary depending on:
    - complexity of the agreement,
    - intellectual property,
    - number of parties involved, and
    - whether the agreement contains language that deviates from Ohio State's approved terms and conditions, requiring additional institutional review.
- After the outside parties and Ohio State sign the agreement, a **PDF version** of the document will be emailed to all parties. The final agreement should be saved for **study records**.

Data Transfer Process:

- Investigators should collaborate with **IT departments** to ensure that data is **secure**. Additionally, any software or platforms being utilized must undergo a risk assessment with **IT Security**. See Institutional Data Policy.

Data Use/Research Data Agreement Signature Routing



Ohio State Contact Information

Office of Innovation and Economic Development (OIED, formerly "TCO"):

- DUA Submission Form: https://innovate.osu.edu/log_in/
- Email: contracts@osu.edu
- General Phone: (614) 247 6633

Office of Sponsored Programs (ERIK):

- https://research.osu.edu/about-us/administration-and-units/office-sponsored-programs

Ohio State Policy and Guidance

Institutional Data Policy:

- https://policies.osu.edu/sites/default/files/documents/2025/02/institutional-data-policy.pdf

Protected Health Information and HIPAA (OSUWMC):

- https://policies.osu.edu/sites/default/files/documents/2025/04/Protected-Health-Information-HIPAA.pdf

Research Data

- https://policies.osu.edu/sites/default/files/documents/2025/03/research-data-policy.pdf

Research Using Protected Health Information ("PHI," OSU-ERIK):

- https://research.osu.edu/research-responsibilities-and-compliance/human-subjects/hipaa-and-human-subjects-research/research

Secure Email (OSUSecure):

- https://it.osu.edu/security/services/secure-email

US Federal Guidance

Definition for Coded-Limited Data Set:

- https://www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/limited-data-set/index.html#:~:text=A%20LDS%20is%20protected% 20health,Telephone%20numbers

Health Information Privacy:

- https://www.hhs.gov/hipaa/for-professionals/special-topics/research/index.html

Methods for De-Identification of PHI:

- https://www.hhs.gov/hipaa/for-professionals/special-topics/de-identification/index.html

Minimum Necessary Requirement:

- https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/minimum-necessary-requirement/index.html

Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule

- https://privacyruleandresearch.nih.gov/pdf/HIPAA_Privacy_Rule_Booklet.pdf