Office of Research Navigation and Compliance

The James



Department of Clinical Operations
The James Cancer Hospital and Solove Research Institute

Material Transfer Agreements (MTAs)

What are MTAs?

A **Material Transfer Agreement** (MTA) is a contractual document that governs the transfer of tangible research materials between two organizations. Associated data may be shared in tandem with materials when the recipient intends to use it for approved research (e.g., IRB protocol, HIPAA).

Any such agreement <u>must</u> 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 MTAs used?

If an Ohio State researcher wants to transfer biospecimens, and if applicable, any health information (identifiable, <u>de-identified</u> and <u>coded-limited</u>) with another institution or company. The Office of Innovation and Economic Development (formerly "TCO"), individually and collaboratively with other departments, review MTAs for research purposes.

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

What do MTAs contain?

- At a minimum, any MTA must contain provisions that address the following:
 - Establish the permitted uses and transfer methods of biospecimens.
 - Detail the specimen types and individual count.
 - Describe the **data types** and **list the elements** of clinical health information that may accompany specimens, both individual samples and in total.
 - Identify the roles on the team that may use or receive the specimens and information.
 - Prohibit the recipient from using or further sharing specimens and data, except as permitted by the agreement or as otherwise permitted by law.
 - Include the appropriate safeguards to prevent unauthorized use or disclosure of information not considered or intended to be the agreement.
 - Prohibit the recipient from identifying the information or contacting individuals.

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MTA 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 transfer in advance of agreement submissions. Human subjects material may delay the process.

Submission Process:

- Investigators and staff may initiate an agreement review with the Office of Innovation and Economic Development (OIED, formerly "TCO") website and choosing 'MTA In' or 'MTA Out' hyperlinks. See the Signature Routing Chart on page 3.
 - For 'MTA In', upload a draft of the agreement provided by the outside party.
 - For 'MTA Out', an agreement will be drafted for you by OIED staff.
- 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 **type and amount** of specimens that will be shared and the **transfer method** (e.g., mail, courier service).
- If applicable, mention the following:
 - Whether the study is IRB-approved. The protocol should include a detailed description
 of the research purpose, specimen and data types, funding and grant mechanisms,
 description of the transfer process, names of the other parties receiving/sending
 specimens, and data access permissions (e.g., who can view protected health
 information (PHI).
 - Highlight the types of data being transferred (identifiable with approved protocol, deidentified or coded-limited.)
 - Detail the transfer process and the individuals involved.
 - Provide only the data reflected within the protocol. See <u>Minimum Necessary</u> <u>Requirement</u>.
 - A list of all the **participating institutions**, organizations, commercial entities, and third parties that will be involved in the transfer process
 - Mention who should have access to any 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.
 - Those 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 MTA. Otherwise, OIED will draft a new agreement to be used.
- Agreements are not active until both parties have signed and agreed upon all listed terms.

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 Provide the name and contact information for the Ohio State representative who handled the negotiations.

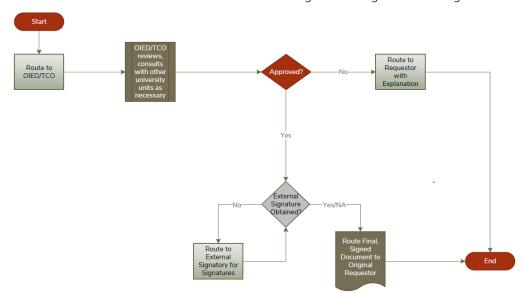
Agreement Review:

- Before specimens can be transferred, MTAs 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.
 - The ICO/TCO facilitates a College of Medicine review of requests for biospecimen transfers external to OSU.
- 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.

Material Transfer Process:

- Sending specimens to a commercial entity may include cost recovery.
- Investigators should collaborate with IT departments to ensure that data is secure according to
 Ohio State's data policy. Additionally, any software or platforms being utilized must undergo a
 risk assessment with IT Security. See <u>Institutional Data Policy</u>.

Material Transfer Agreement Signature Routing



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Ohio State Contact Information

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

MTA submission form: https://innovate.osu.edu/log_in/

Email: contracts@osu.eduGeneral Phone: (614) 247 6633

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):

• <a href="https://research.osu.edu/research-responsibilities-and-compliance/human-subjects/hipaa-and-human-subjects-research/res

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

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Minimum Necessary Requirement:

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

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

• https://privacyruleandresearch.nih.gov/pdf/HIPAA Privacy Rule Booklet.pdf