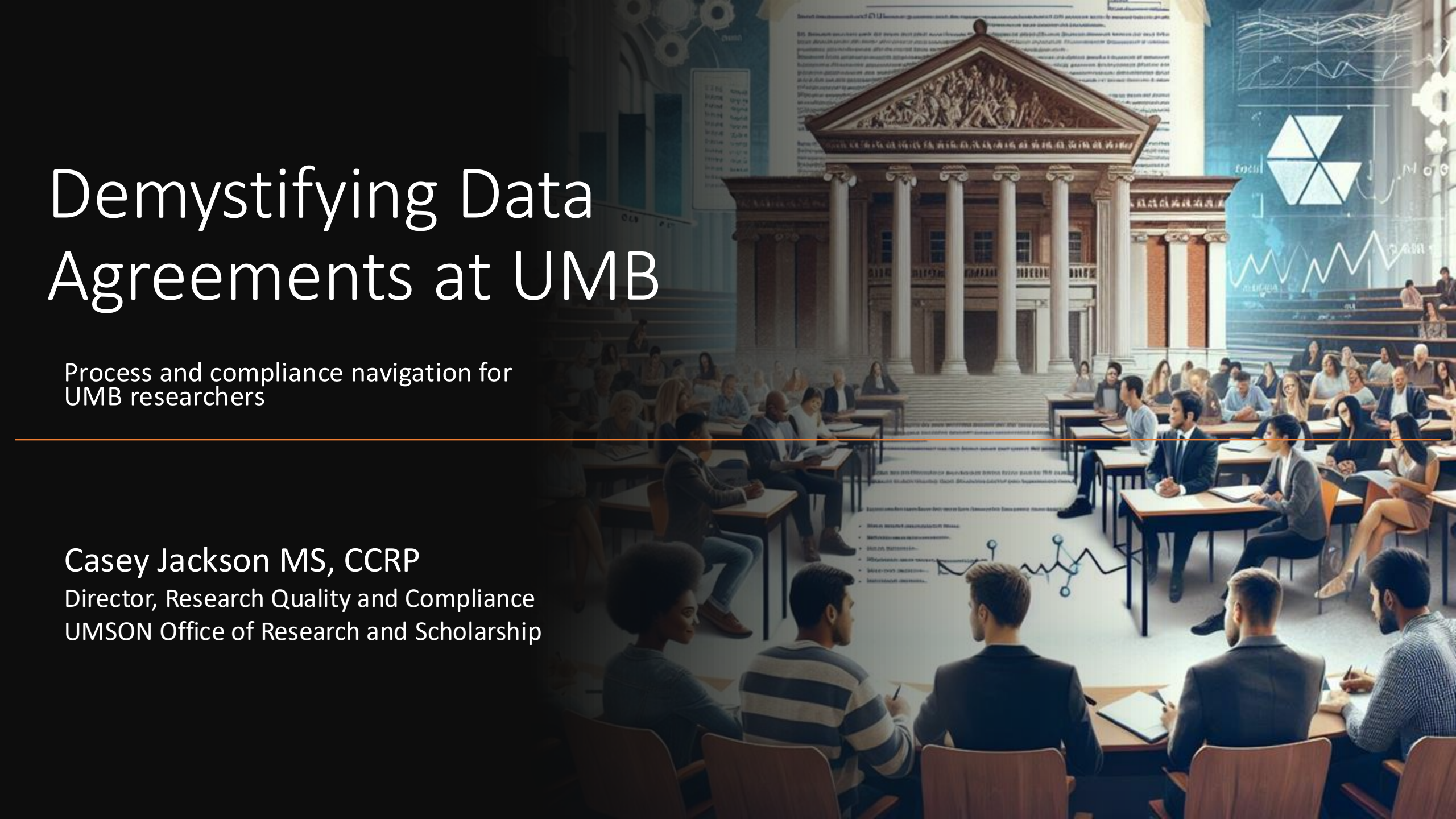
Demystifying Data Agreements at UMB

Process and compliance navigation for UMB researchers



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ALL THE QUESTIONS!



Do I need a data agreement?	Who is involved?	Who signs it?	Who creates it?	Who can help me?
What do I need?	When do I start?	Where do I submit it?	Where do I store it?	Why do I need it?
How do I execute it?	How long does it take?	How long does it last?	How do I ensure compliance with it?	What happens if the agreement is broken?

Types of Data

- **PHI vs PII** (both are data including identifiers)
  - PHI: Protected Health Information (protected under HIPAA)
  - PII: Personally Identifiable Information (not protected under HIPAA)

- **Non-PII** – Data that cannot be used on its own to identify someone

- **Identifiable vs. Coded vs. De-identified vs. Anonymous**
  - Identifiable: Data that has identifiers included (PHI and/or PII)
  - Coded: [SEPARATE CODE KEY CAN IDENTIFY] Data that accessed and recorded identifiers onto a separate code-key linking the identifiers to a non-identifying code. Data set only has code, not the identifiers
  - De-identified: [NO IDENTIFIERS ATTACHED] Data that accessed identifiers but did not record identifiers (or fully stripped identifiers from data set).
  - Anonymous: [NEVER IDENTIFIED] Data that never accessed identifiers therefore could not record identifiers

Acronyms

DSA (Data Sharing Agreement)

DTA (Data Transfer Agreement)

DUTA (Data Use and Transfer Agreement)

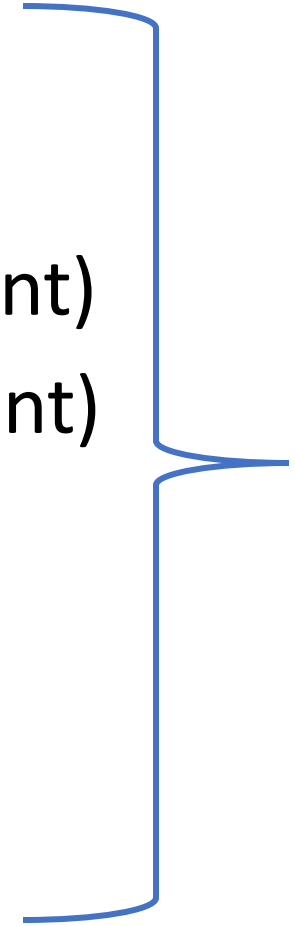
DTUA (Data Transfer and Use Agreement)

DPA (Data Processing Agreement)

DUA (Data Use Agreement)

LDS (Limited Data Set)

BAA (Business Associate Agreement)



Similar, but different!
May or may not be HIPAA associated

Approach Data Sharing with Caution

Consider:

-Not best practice to actively promote sharing of data.

Why?

Potential to create contractual liabilities for UMB

What is a DUA?

CICERO Says:

A Data Use Agreement (DUA) is a legal binding agreement between the Operating Division (OPDIV) and an external entity (e.g., contractor, private industry, academic institution, other Federal government agency, or state agency), when an external entity requests the use of personal identifiable data that is covered by a legal authority, such as the Privacy Act of 1974, Economy Act, Government-wide User Charge Authority, Intergovernmental Cooperation Act, "Special Studies" statute, Joint Project Authority, and the Clinger-Cohen Act. The agreement delineates the confidentiality requirements of the relevant legal authority, security safeguards, and the OPDIV's data use policies and procedures. The DUA serves as both a means of informing data users of these requirements and a means of obtaining their agreement to abide by these requirements. Additionally, the DUA serves as a control mechanism for tracking the location(s) of the OPDIV's data and the reason for the release of the data. A DUA requires that a System of Records (SOR) be in effect, which allows for the disclosure of the data being used.

TLDR: A DUA is a tracking mechanism and security and use contract between parties that want to share identifiable data

What is an LDS?

CICERO says:

A Limited Data Sets (LDS) is an exception to the Privacy Rule requirement for an authorization from the subject for research use of protected health information.
A LDS does NOT include the following identifiers: Name; Postal address information, other than town or city, State, and zip codes; Telephone numbers; Fax numbers; Electronic mail addresses; Social security numbers; Medical record numbers; Health plan beneficiary numbers; Account numbers; Certificate/license numbers; Vehicle identifiers and serial numbers, including license plate numbers; Device identifiers and serial numbers; Web Universal Resource Locators (URLs); Internet Protocol (IP) address numbers; Biometric identifiers, including finger and voice prints; and Full face photographic images and any comparable images.
A LDS may contain, for example: Dates of birth; Dates of death; Dates of service; Town or city; State; Zip code
The difference between a LDS and de-identified information is that a LDS may contain dates and certain geographic information associated with an individual that are absent from de-identified information.

TLDR: An LDS is a data set that may contain dates and geographic info specific to a person, but no other identifiers

What is a BAA?

A Business Associate Agreement (BAA) is typically used when fully identifiable personal health information (PHI) is being shared by/between HIPAA covered entities for qualifying service purposes

BAAs are meant for specific circumstances and if those circumstances are not met, a Data Use Agreement (DUA) should be used.

Note! The BAA is worked out between SPA/CCT and University legal. The researcher is not involved in this process.

https://www.umaryland.edu/spa/developing-proposals/unfunded-agreements/hipaa-baas/#:~:text=A%20Business%20Associate%20Agreement%20(BAA,(DUA)%20should%20be%20used

How do you know if you need a data agreement?

Receiving data from an entity external to UMB/UMMC ☑

AND/OR-

Sharing data outside of UMB/UMMC ☑

Yes, even if the external partner is on your approved IRB application, you need a DUA to share the data with them!

NOTE!

SPA/CCT, NOT the PI/researcher, determines whether a data agreement is needed

Prepare for a data agreement request by knowing:

- Are you providing or receiving the data?
- Was there an existing data management plan in place? *If so, obtain it for review*
- What is the original source of the data?
  - If HS research, did participants consent to sharing for future purposes/other parties?
  - If HS research, is there an approved IRB application?
  - Are the data from persons living in the European Union (EU)?
- What kind of data is it? (Consult data classification tool FDP)
- Is the data related to research, procurement, clinical, or neither?
- Is the data from UMMS (HIPAA) or UMB (may or may not be HIPAA)?
- Does the data contain identifiers?
- How will the data be accessed? managed? secured? What happens to the data upon completion?
- Is the proposed project unfunded or funded (corporate, non-profit, academic, government, etc.)?
- Who is your school/department research administrator and what is their contact?

How do you get a data agreement document?

DO NOT USE/CREATE YOUR OWN TEMPLATE!

DO NOT NEGOTIATE THE TERMS!

If <u>receiving</u> data:

Use the template provided by the other entity (can offer our template if they don't have one). PA/CCT/SSAS/OUC/Informatics Core will review/negotiate/sign the template provided by the other entity.

If <u>sharing</u> data:

SPA/CCT/SSAS/OUC/Informatics Core will identify the appropriate template and negotiate

Who creates the data agreement?

Determine Appropriate Routing

Is this related to UMB or UMMC?

- If UMMC, contact informatics core ICTR (research) or department head (non-research)
- If UMB, see below:

  Is this related to a research project?

  - If yes:
    - is the research corporate funded?
      - If yes, send to Center for Clinical Trials and Corporate Contracts (CCT).
      - If no, is the research funded by non-profit or government or unfunded?
        - If yes, send to Sponsored Programs Administration (SPA).
        - If it's not related to a research project, is it related to a procurement? If so, route to Strategic Sourcing and Acquisition Services (SSAS)
  - If no: (it's not related to a research project or procurement)
    - route to your unit head to send to the Office of University Counsel (OUC).

Routing:
Funded Research (Corporate)

CCT: Either the school or department assigned research administrator, or the PI will work with CCT (UMBIZ)

Examples:

-A pharma company wants to obtain UMMS clinical data for a specific disease population (registry study).

-Pharma sponsored vaccine trials, oncology trials, etc.

Routing:
Funded Research (Non-Profit/Government/Academic, etc.)

SPA (UMB): Work with school/department assigned research administrator to submit to SPA via Kuali.

Informatics Core (UMMS): Either the school or department assigned research administrator, or the PI will work with UMMS (informatics core)

Example:

A researcher from an external university wants to use data from an investigator-initiated research study completed at UMB. Participants in the study consented to its further use and sharing. The proposed data use project is grant funded. The data may or may not have PII attached to it.

Routing:
Unfunded Research (UMB)

SPA (UMB): Work with school/department assigned research administrator to complete request (fill out required form) and attach the form in Kuali.

Informatics Core (UMMS): Either the school or department assigned research administrator, or the PI will work with UMMS (informatics core)

Example:

A researcher from an external university wants to use data from a department funded research study completed at UMB. Participants in the study consented to further use and sharing of data. There is no funding for the proposed data use project. The data may or may not have PII attached to it.

Routing:
Research Procurement (UMB)

SSAS: Work with school/department assigned research administrator or research office to complete a procurement request

Examples:

Researchers who wish to **purchase**:

- a data set
- a CTMS
- research devices/lab equipment

Note! If funds are leaving UMB, procurement is involved as well

Routing:
Non-clinical, non-research, non-procurement (UMB)

OUC: This is very rare, but if your project doesn't involve clinical, research, or procurement, reach out to your department head who will then find the appropriate path and contact OUC if necessary.

Example: Educational (non-clinical) Quality Improvement (QI) project

What happens next?

Appropriate party will review, negotiate if necessary, and sign the agreement.

CCT: via email/department head; UMBIZ

SPA: via Kuali **(SPA establishes award in Kuali, and handles negotiations/distribution of agreement via email)**

SASS: via email/department head

OUC: via email/department head

DO NOT SIGN ON BEHALF OF UMB!

Timeline
(How long does this take?)

Weeks? Months?

Depends on many factors:

- Quality/appropriateness of submission
- Other negotiating parties
- Staffing
- Complexity of request

Tip: Stay in contact with your research administrator/contracts department!

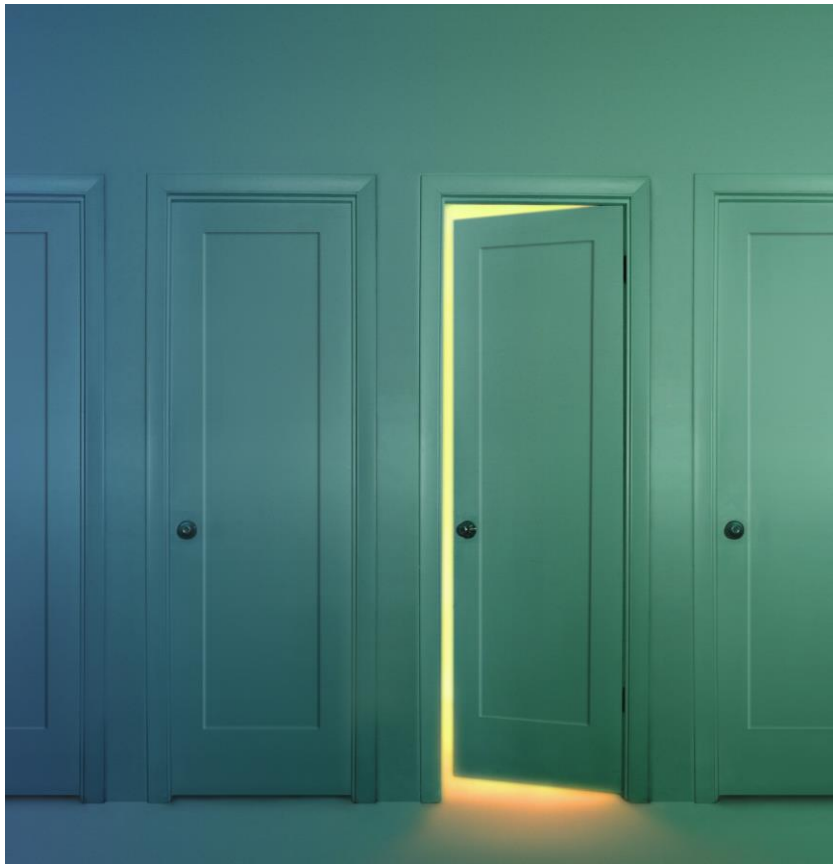
What About “Pass-through” DUAs?

DUA’s for publicly available non-PII data requested on behalf of an individual at UMB, but independent of UMB.

Examples:

- Statistics students who wish to obtain data for a class project
- PhD students obtaining a dataset for their dissertation

Best Practice: the policies/procedures/terms and conditions should be printed to pdf and submitted for the review of the appropriate office (SPA, CCT, etc.).



Compliance

- Early on, involve the School/Department IT staff (and CITS) to ensure data security is appropriately considered/addressed/negotiated/managed, etc.
- Cannot share data until agreement final and IRB/HRPO determination (HSR or NHSR) obtained.
- Cannot misalign with data management plan (DMP).
- You must adhere to the DUA terms, associated regulations, and the IRB approved protocol/consent form (latter if applicable).
- SRE use encouraged for PII, required for UMMS Epic clinical data (PHI).
- Clinical access to EPIC should not be used for research purposes.

What happens if there is a problem?

No agreement vs. broken agreement:

No agreement = regulatory risks.

Broken agreement = contractual risks.

Risks involved in improperly handling data:

- Potential data breaches (regulatory fines, notices to victims, media coverage).
- Negligence claims and lawsuits.
- Exclusion of student from site.
- Loss of access to data.
- Inability to publish results.
- Disciplinary action.

Who to contact:

Your supervisor and the Center for Information Technology (CITS). Contact emails @

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How do I execute it?	How long does it take?	How long does it last?	How do I ensure compliance with it?	What happens if the agreement is broken?

Some of the answers…

Do I need a data agreement? -If sharing/receiving data outside of UMB/UMMC, YES.
Who is involved? - your research administrator and SPA/CCT/SASS/OUC (situation dependent)
Who signs it? - Not you!
Who creates it? -Not you!
Who can help me? - your research administrator
What do I need? -See slide 10
When do I start? - ASAP
Where do I submit a request? -See slide 13
Where do I store it? -Consult the final agreement
Why do I need it? -Because you value your job, the law, privacy, and the University
How do I execute it? -You don't! See slide 13
How long does it take? –Could take weeks to months
How long does it last? -Consult the final agreement
How do I ensure compliance with it? -Consult the final agreement, talk with your IT staff/CITS
What happens if the agreement is broken? -Consult the final agreement, talk with your IT staff/CITS

Contacts/Resources

Sponsored Programs Administration (SPA) through KUALI

Center for Clinical Trials and Corporate Contracts (CCT) through UMBIZ

Strategic Sourcing and Acquisition Services (SASS) through Procurement

Office of University Counsel (OUC) through OUC Website

Data Security: Secure Research Environment

Appreciations

This presentation was developed and vetted through many leaders who patiently addressed my tireless questions and “what-if” scenarios. Without their time and expertise, this presentation would not be possible. I would like to thank the following persons for their dedication to data compliance and willingness to get messy with me as I assembled this talk:

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