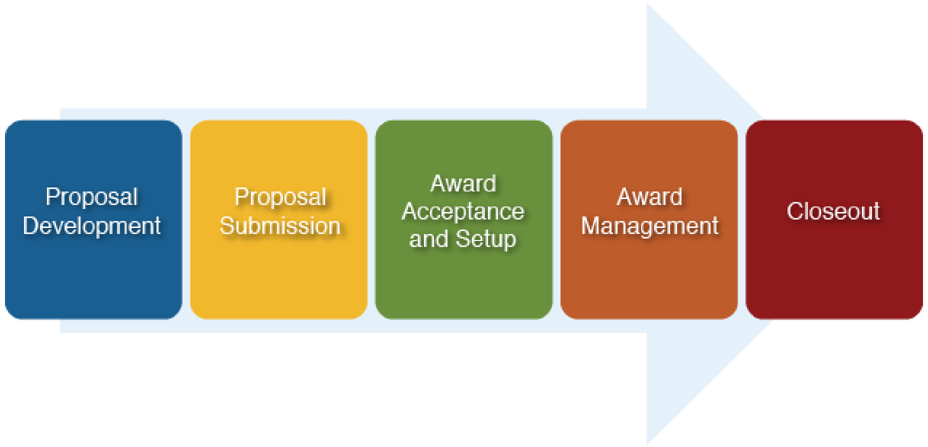
Non-Financial Agreements

SPA Certificate Series

Sponsored Programs Administration
University of Missouri

Agenda

-Agreement Types
-Uses
-Pertinent Provisions
-Submission & Process
-Resources



Proposal Development

Proposal Submission

Award Acceptance and Setup

Award Management

Closeout

By The Numbers (FY25)

- NDAs - 216
- MTAs - 433
- DTUAs - 102
- Other - 42

TOTAL = 793

Nondisclosure Agreements

NDA – Nondisclosure Agreements

CDA – Confidentiality Agreements or Confidential Disclosure Agreements

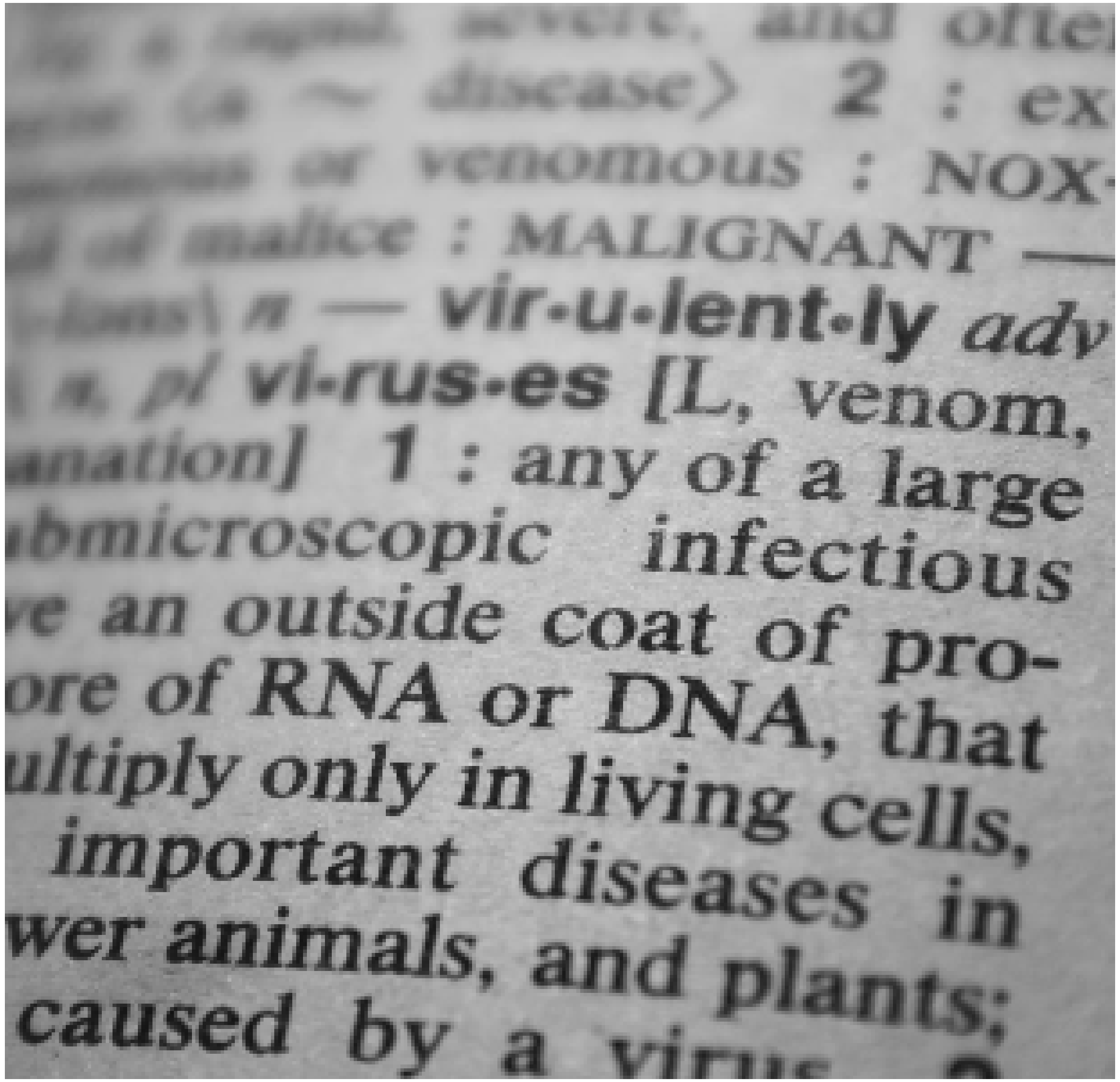
PIA – Proprietary Information Agreement

Secrecy Agreement

nondisclosure agreement
noun

- : an agreement in which a person (such as an employee) agrees to keep information (such as a trade secret) confidential
- called also confidentiality agreement, NDA
- The first known use of nondisclosure agreement was in 1959

Source: Merriam-Webster



ing a rapid, severe, and ofte
(a ~ disease) 2 : ex
ous or venomous : NOX-
of malice : MALIGNANT —
lens\ n — vir·u·lent·ly adv
n, pl vi·rus·es [L, venom,
nation] 1 : any of a large
bmicroscopic infectious
ve an outside coat of pro-
ore of RNA or DNA, that
ultiply only in living cells,
important diseases in
wer animals, and plants;
caused by a virus

Elements

- Parties to the agreement
- Definitions
- Obligations
- Scope
- Timeframe
- Exclusions
- Remedies

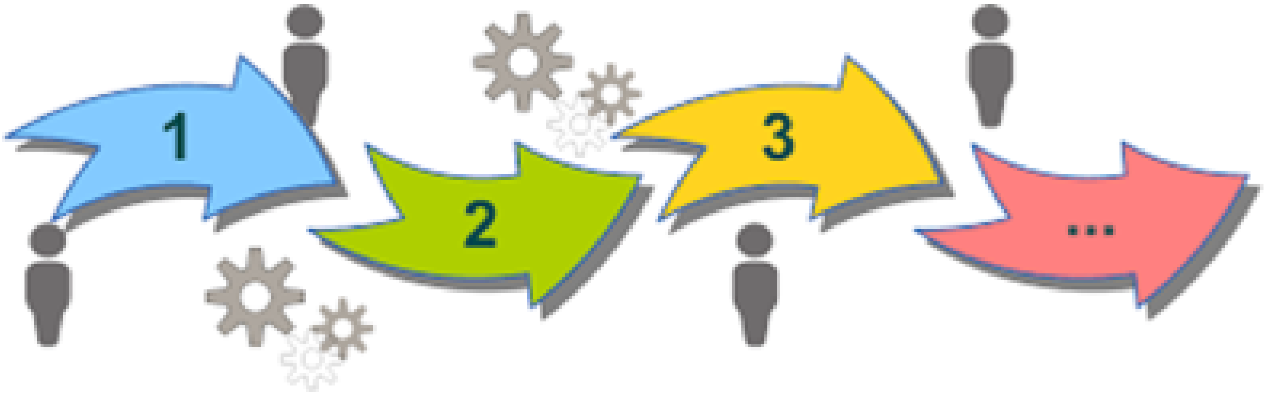
WHY?

- Protection of intellectual property, data, unpublished research, or other valuable information

- Creates legal obligation to keep such information confidential

- Future sponsored research agreement or possible licensing agreement

CDA Process



- Investigator Initiated
  - We send MU’s template
  - The Sponsor makes changes
  - We review and accept the changes or make counter proposals and General Counsel reviews and makes changes or approves as to legal form
  - We sign and save the agreement
- Sponsor Initiated
  - The Sponsor generally sends a template
  - We review and strike language that is problematic for the University, make changes and get General Counsel’s review and changes
  - The Sponsor reviews our changes and accepts them or we negotiate
  - We sign and save the agreement

Material Transfer Agreements

A binding contract in which one party agrees to provide physical materials to another party for testing, evaluation, and/or experimentation

When?

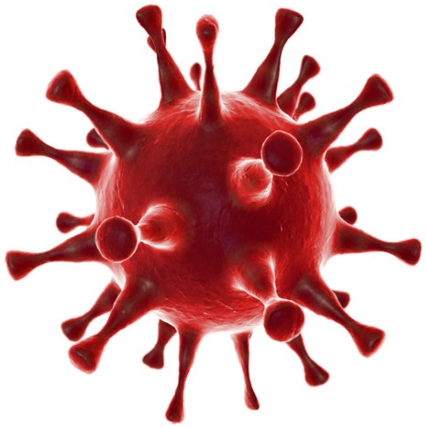
Not Needed (usually)

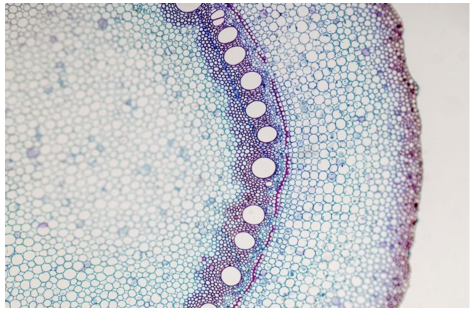
- Transfer of unmodified, naturally occurring, non-hazardous materials that do not contain any human/animal tissue
- Commercially available materials
- Transfer of documents
- Transfer of purchased equipment/instrumentation for repair or replacement

Agreement Necessary

- If outgoing material relates to a patentable invention
- University/PI needs to retain control over the material and its research use
- When the transfer of material isn’t covered by another agreement

TYPES





MTA Key Terms

- Liability and intellectual property language (protects the provider)
- Scope of use for the materials, including further dissemination
- Disposition of materials upon completion of research/MTA term
- Ownership of material and any modifications and derivatives made by the recipient
- No commercial rights
- Provider should have no rights to inventions made by the recipient in the use of materials (underlying/embedded material still belongs to provider)

Incoming MTA Requests

- Other Party Contact Information
- Type of Material

✓ Biological

✓ Chemical

✓ Genetically Modified Organisms

✓ Human Tissue

✓ Other

- Description & Quantity
- Will the material/modified material become incorporated into a new research material, including those described in any of your preexisting or anticipated disclosures of intellectual property to the University?

Outgoing MTA Requests

- Other Party Contact Information
- Type, Quantity, and Description of Materials
- Where was the material generated?
- What was the source of funding used to create the material?
- Is the material described in an Invention Disclosure on file with Technology Advancement?
- Will the material/modified material become incorporated into a new research material, including those described in any of your preexisting or anticipated disclosures of intellectual property to the University?

Data Transfer and Use Agreements

DUA – Required by HIPAA when a covered entity shares a Limited Data Set
DTA – Data Transfer Agreement
DSA – Data Sharing Agreement
DTUA – Data Transfer & Use Agreement

What is a Data Use Agreement?

A Data Use Agreement (DUA) is a legal contract between the entity that owns or controls access to a data source, typically a dataset or database, and a secondary entity that will receive the data, or a subset of it, for reuse for a specific project or purpose.

A DUA outlines the terms, conditions, and limitations of how the shared data may be used.

Courtesy:

NIH National Library of Medicine

https://www.nnlm.gov/guides/data-glossary/data-use-agreement

When do we need a DUA?

<u>For Human Subjects Data</u>:

- Disclosing for research purposes;
- Individual authorization for disclosure to this recipient is not/has not been obtained;
- Disclosure is permitted under an IRB-approved protocol (for human subject research); or
- The researcher is disclosing or receiving a “limited data set” of personal health information, as defined under HIPAA.

When do we need a DUA?

For Non Human Subjects Data:

If no other contract concerning the transfer of the data exists between Provider and Recipient and:

- Data is not in the public domain and the Provider wishes to limit use or distribution of the data in some way, and
- Recipient intends to use the data for **research** purposes

But why do I need a DUA?

It's the law! (When sharing **personally identifiable information (PII)):**

- Health Insurance Portability and Accountability Act (HIPAA)
- Family Educational Rights and Privacy Act (FERPA)
- General Data Protection Regulation (GDPR) for contracting with European member states (EU Zone); copy cat GDPR terms from non-EU member state countries.
- Some State Privacy laws
- Institutional policies
- Preference to have a Contract

Data Types

Human Subjects Data

HIPAA Regulated Data - PHI/Limited Data Set, De-Identified

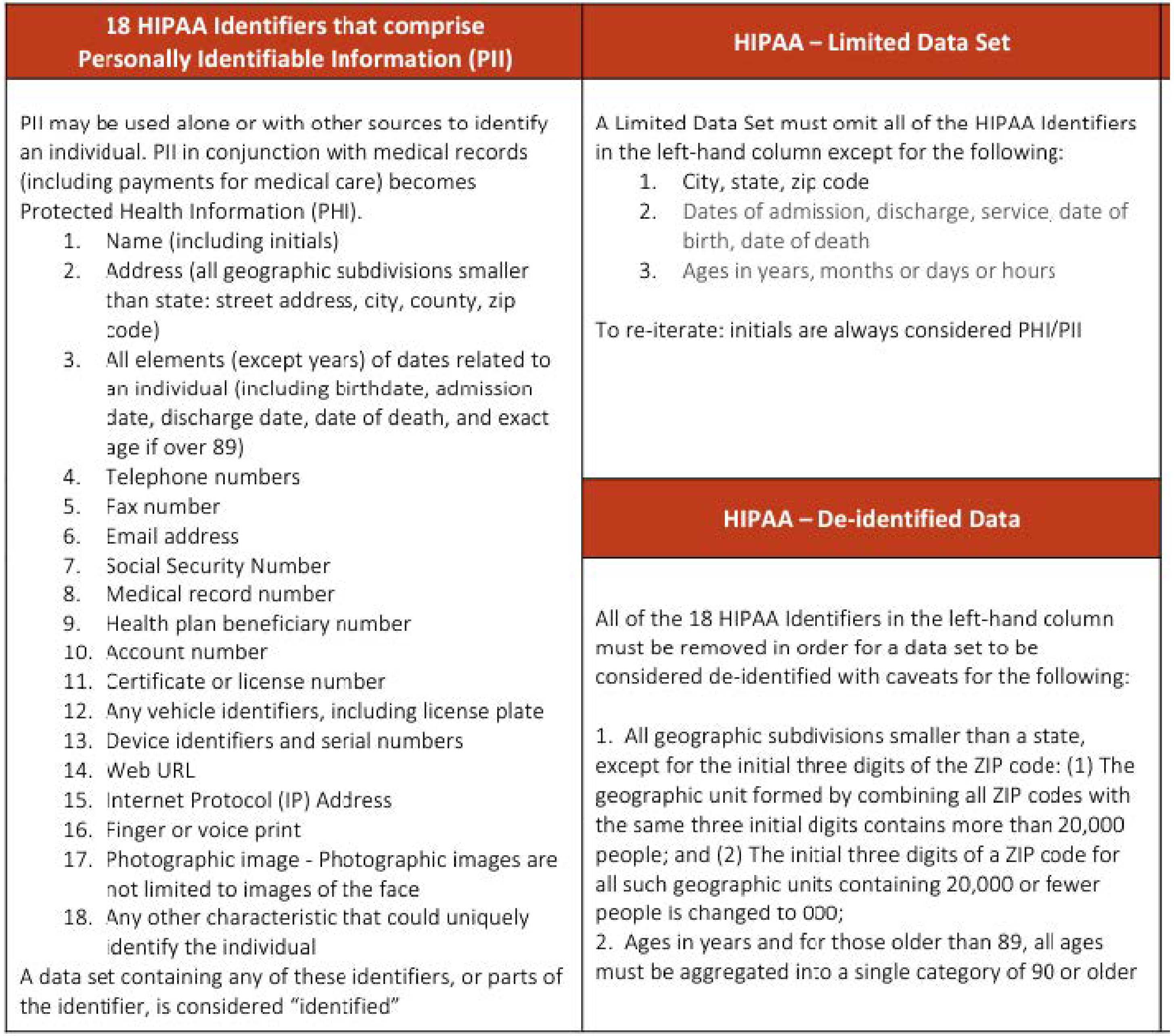
Common Rule/Research Regulated Data – Personally Identifiable Information

FERPA Regulated Data – Personally Identifiable Information

PII Not patient-related

HIPAA – Protected Health Information (PHI)

Any information **in the medical record** or designated record set that can be used to identify an individual and that was created, used, or disclosed in the course of providing a health care service such as diagnosis or treatment.



<table>
<tr><th>18 HIPAA Identifiers that comprise Personally Identifiable Information (PII)</th><th>HIPAA – Limited Data Set</th></tr>
<tr><td rowspan="3">PII may be used alone or with other sources to identify an individual. PII in conjunction with medical records (including payments for medical care) becomes Protected Health Information (PHI).
1. Name (including initials)
2. Address (all geographic subdivisions smaller than state: street address, city, county, zip code)
3. All elements (except years) of dates related to an individual (including birthdate, admission date, discharge date, date of death, and exact age if over 89)
4. Telephone numbers
5. Fax number
6. Email address
7. Social Security Number
8. Medical record number
9. Health plan beneficiary number
10. Account number
11. Certificate or license number
12. Any vehicle identifiers, including license plate
13. Device identifiers and serial numbers
14. Web URL
15. Internet Protocol (IP) Address
16. Finger or voice print
17. Photographic image - Photographic images are not limited to images of the face
18. Any other characteristic that could uniquely identify the individual
A data set containing any of these identifiers, or parts of the identifier, is considered "identified"</td><td>A Limited Data Set must omit all of the HIPAA Identifiers in the left-hand column except for the following:
1. City, state, zip code
2. Dates of admission, discharge, service, date of birth, date of death
3. Ages in years, months or days or hours
To re-iterate: initials are always considered PHI/PII</td></tr>
<tr><th>HIPAA – De-identified Data</th></tr>
<tr><td>All of the 18 HIPAA Identifiers in the left-hand column must be removed in order for a data set to be considered de-identified with caveats for the following:
1. All geographic subdivisions smaller than a state, except for the initial three digits of the ZIP code: (1) The geographic unit formed by combining all ZIP codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a ZIP code for all such geographic units containing 20,000 or fewer people is changed to 000;
2. Ages in years and for those older than 89, all ages must be aggregated into a single category of 90 or older</td></tr>
</table>

HIPAA – Limited Data Set

- A Limited Data Set must omit all of the HIPAA Identifiers except for the following:

  1. City, state, zip code

  2. Dates of admission, discharge, service, date of birth, date of death

  3. Ages in years, months or days or hours

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- Ages in years and for those older than 89, all ages must be aggregated into a single category of 90 or older

What is Common Rule data?

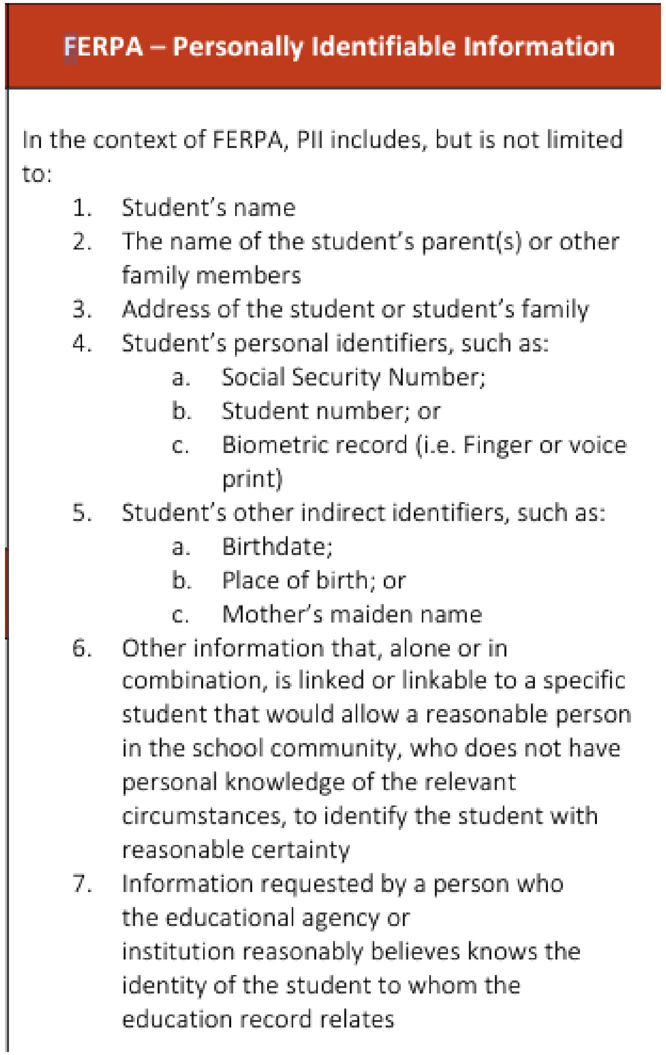
- **Research Data (Consented)**

- The "**Common Rule**" is the popular term for the Federal (U.S.) Policy for the Protection of Human Subjects , 45 CFR part 46 , which outlines the criteria and mechanisms for IRB review of human subjects research.
- Common Rule permits an IRB grant of exemption from review if the data is existing or publicly available, unless a re-identification code is used. The Privacy Rule permits use or disclosure for research with individual patient authorization or an IRB or privacy board waiver of authorization.
- An example of Common Rule data could be datasets showing taste preferences of human subjects when comparing steak, chicken and pork, previously collected from adult men. No identifying information will be shared, and none of the data were collected from patients or were derived from medical records.
  - This is not medical/patient data, participants were recruited from the community rather than from clinical referrals.

What is FERPA data?

- Applicable to educational records which are those of an educational agency/institution or party acting on its behalf AND “directly related” to a student (34 C.F.R. 99.3)
- Also covers medical records of students instead of HIPAA (has its own HIPAA within FERPA for student health center records, etc.)
- Must put a DUA in place if disclosing (PII) identifiable student data:
    - **Example**–demographics, grade level, school –these may all be de-identified by themselves but if you disclose all and there is only one Asian-American female in 10th grade at that school, it becomes identifiable FERPA data
    - De-identification is considered successful when there is no reasonable basis to believe that the remaining information in the records can be used to identify an individual

What is FERPA data?



FERPA – Personally Identifiable Information

In the context of FERPA, PII includes, but is not limited to:

1. Student's name
2. The name of the student's parent(s) or other family members
3. Address of the student or student's family
4. Student's personal identifiers, such as:
   a. Social Security Number;
   b. Student number; or
   c. Biometric record (i.e. Finger or voice print)
5. Student's other indirect identifiers, such as:
   a. Birthdate;
   b. Place of birth; or
   c. Mother's maiden name
6. Other information that, alone or in combination, is linked or linkable to a specific student that would allow a reasonable person in the school community, who does not have personal knowledge of the relevant circumstances, to identify the student with reasonable certainty
7. Information requested by a person who the educational agency or institution reasonably believes knows the identity of the student to whom the education record relates

What is PII Non-patient Data?

- Research data or non-health related Personally Identifiable Information (PII). Any representation of information that permits the identity of an individual to whom the information applies to be reasonably inferred by either direct or indirect means.
- Examples:
  - Data on speeding tickets including **VIN**
  - Data on browsing habits/websites visited, including the **IP address and location**

Checklist: What information do I need to have to draft my data use agreement?

DATA PROVIDER	**DATA RECIPIENT**
• Principal Investigator • Administrative Contact • Description of Data • Description of Project • Is IRB review and determination required? • Is the Provider Organization in a foreign country?	• Principal Investigator • Administrative Contact • What Data will be collected • What will Recipient do with the data? • Is the Recipient Organization in a foreign country?

Compliance Considerations for Nonfinancial Agreements

- Research Security and Compliance (Export Controls and Sanctions)
- Human Subjects Research (IRB)
- Technology Advancement
- Conflict of Interest
- Privacy Office
- Environmental Health & Safety
- IT Security
- Information Security

Agreement?

An investment firm reads about a faculty's research profiled in the news and reaches out to the faculty member to learn more about the technology. They are interested in assisting in the commercialization of a rapid bacterial detection test.

Agreement?

Professor Zach worked with a former MU faculty member, a co-inventor on one of his issued patents, on a collaborative project and wishes to continue their collaborative research. Professor Zach plans to share his patented software with the former faculty member, who will analyze data related to the project. The former faculty will share analyzed data and newly acquired data with Professor Zach.

Agreement?

Researcher A from the University of Oregon and Researcher B from the University of Arizona want to collaborate with MU’s NSRRC (National Swine Resource and Research Center) on making a genetically modified pig model for an NIH funded project.

Agreement?

Company One is interested in licensing a soybean line from MU. They have requested in house data from MU's breeder.

Requesting a Non-financial agreement

- Submit a request in eCompliance at https://ecompliance.missouri.edu/ospa/agreement-intakes

- Email agmts@missouri.edu

- Call:

  Sasha Lawson, 882-0104

  Lindsey Conrad, 882-1576

  Chase Bunger, 882-0275

  Sean Murphy, 882-7560

Non-financial Agreement Resources

- https://research.missouri.edu/index.php/sponsored-programs-administration/confidentiality-data-use-and-material-transfer-agreements

- https://autm.net/surveys-and-tools/agreements/material-transfer-agreements

- https://thefdp.org/demonstrations-resources/dtuas/

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

- https://privacyruleandresearch.nih.gov/pr_08.asp#8a

- https://www.umsystem.edu/ums/is/infosec/information-security-risk-management