

Data Use Agreements

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What does a DUA address?

- Commonly used for the transfer of data between two or more parties.
- Memorializes the handling, protections and liabilities for each party in regards to their obligations toward the data and each other.
- Different agreement terms for different data types
 - De-Identified Data
 - Personally Identifiable Information
 - Protected Health Information
 - Limited Data Set
 - Other

Different standards of De-Identification

- Different standards and levels of de-identification exist, common examples include:
 - 46 CFR 45 (Common Rule)
 - HIPAA
 - Anonymized
- As applicable, OIS and IRB can assist with implementing the correct de-identification standard.

Different types of data sets

18 HIPAA Identifiers that comprise Personally Identifiable Information (PII)	HIPAA – Limited Data Set	FERPA – Personally Identifiable Information
<p>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).</p> <ol style="list-style-type: none"> 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 <p>A data set containing any of these identifiers, or parts of the identifier, is considered “identified”</p>	<p>A Limited Data Set must omit all of the HIPAA Identifiers in the left-hand column except for the following:</p> <ol style="list-style-type: none"> 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 <p>To re-iterate: initials are always considered PHI/PII</p>	<p>In the context of FERPA, PII includes, but is not limited to:</p> <ol style="list-style-type: none"> 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: <ol style="list-style-type: none"> 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: <ol style="list-style-type: none"> 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
	<p>HIPAA – De-identified Data</p> <p>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:</p> <ol style="list-style-type: none"> 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 	

Information commonly required for a DUA

- What type of data is being exchanged?
- Is there a description of the data available?
- Is the exchange bilateral or unilateral?
- Where did the data come from, received from a 3rd party or generated in house?
- If applicable, is an IRB protocol in place?
- Reliance agreements necessary?
- If applicable, is the Informed Consent Form available?

Information commonly required for a DUA (cont.)

- Will NU have access to any key or code?
- How will the data be used?
- Are another party's data required to be included in any deliverables to a 3rd party?
- Data providers have a wide spectrum of additional requirements for specific situations.
- Will it be necessary to link the data with any other data set(s)?

DUA review process

- NU-RES resolves DUAs either as stand alone agreements or incorporates the terms into a main agreement (e.g., a DUA may be resolved through a subaward, or may be executed independently).
- NU-RES reviews the agreement and information submitted via eCLAWs and will connect with the Principal Investigator/Researcher for any additional information required.
- As applicable, NU-RES, IRB and OIS connect

Additional consideration

- Irregular sources of identifying information (e.g., photos, videos, interviews)
- Obligations as a Principal Investigator on an award, do you need programmatic access to identifiable information?
- When is something being de-identified? Before receipt by a party, or is identifiable information being provided and the receiving party de-identifying it?
- Is the data being stored internally or managed by a 3rd party?

Expect change

- Privacy laws are ever evolving, as are policies and practices of NU and various funding institutions. The last decade has seen the revise of (and many revisions to) the GDPR, California implemented the CCPA, and the New York has the Shield Act, to name a few.
- NU policies, and the policies of those we exchange data with, will continue to evolve along with the research sphere.

What is the role of the IRB?

- The IRB is not responsible for ensuring you have a data sharing agreement. However, they may alert you of the need for a data sharing agreement during IRB review. Additionally, in order to make the appropriate regulatory determinations, the IRB may ask to see a draft or executed data sharing agreement before issuing effective approval of your IRB application.
- If your study requires IRB approval, you should not share any data under an executed data sharing agreement until you have obtained IRB approval to do so.
- It is the responsibility of the study team to ensure a modification to the approved protocol is submitted if the nature of the data or the data sharing changes after an IRB determination has been made.

Best practices for an efficient process

- The amount of time needed to fully execute a contractual agreement depends on many factors, including the type and number of institutions that will be involved, the type of data being shared, and whether consultation with other offices or entities is needed.
- The most important action you can take to promote an efficient process is to plan ahead. Develop a sharing plan at the time of protocol development, and ensure the consent form and/or authorization address any potential future sharing.
- To classify your data, first consider which laws or regulations apply to your data. An agreement may be required by law if the data you are receiving are covered by HIPAA, FERPA, or GDPR.

Sample Scenarios

- NU collaborates with institution B on a human subject research, institution B helps NU to analyze de-identified data. NU will obtain IRB approval. Institution B will not obtain IRB approval because institution B is not engaged in the research. A DUA is NOT required for institution B to receive de-identified data from NU.
- NU collaborates with institution B on a project, both institutions will exchange data (including identifiable data) with each another. Both institutions will obtain IRB approval. A DUA is NOT required for institution B to receive data from NU because institution B is collaborating with NU for the same research project.
- NU plans to release data to institution B for secondary use. NU is not involved in the outside institution's research other than to share data. A DUA is required for institution B to receive data from NU because the sharing is for secondary use.

Resources

- [MIT](#)
- [Northwestern University](#)
- [University of Wisconsin – Madison](#)
- [Northeastern University – Research Enterprise Services](#)
- [Northeastern University – Human Research Protection Program/IRB](#)