



Data Use Language in DUAs and contracts

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Why is this necessary?

THE HIPAA PRIVACY RULE ESTABLISHED WAS CODIFIED IN 2020 FOR MOST FEDERAL AGENCIES. IT DETERMINED THE CONDITIONS UNDER WHICH PROTECTED INFORMATION MAY BE USED OR DISCLOSED BY COVERED ENTITIES FOR RESEARCH PURPOSES. THIS FALLS UNDER THE COMMON RULE, 45 CFR PART 46, SUBPART A. PER THE COMMON RULES, TO MINIMIZE RISK, USF MUST HAVE AN ADEQUATE PLAN TO PROTECT FROM IMPROPER DISCLOSURE, AN ADEQUATE WRITTEN ASSURANCES THE PHI WILL NOT BE USED OR DISCLOSED EXCEPT WHERE REQUIRED BY LAW.

[HTTPS://WWW.HHS.GOV/HIPAA/FOR-PROFESSIONALS/SPECIAL-
TOPICS/RESEARCH/INDEX.HTML](https://www.hhs.gov/hipaa/for-professionals/special-topics/research/index.html)

What is the purpose of a DUA?

A DUA ADDRESSES IMPORTANT ISSUES, SUCH AS LIMITATIONS ON USE OF DATA, LIABILITY FOR HARM ARISING FROM USE OF DATA, PUBLICATION, AND PRIVACY RIGHTS ASSOCIATED WITH TRANSFER OF CONFIDENTIAL OR PROTECTED DATA. DATA SECURITY MEASURES MUST BE MET IN ORDER TO KEEP DATA SECURE.

A DUA DESCRIBES HOW TO ACCESS, STORE, PROTECT, USE, AND TRANSMIT DATA , SUCH AS PROTECTED HEALTH INFORMATION (PHI), PERSONALLY IDENTIFIABLE INFORMATION (PII), LIMITED DATA SETS, AND/OR PROPRIETARY (CONFIDENTIAL) INFORMATION.

A DUA PREVENTS INAPPROPRIATE USE OF PROTECTED OR CONFIDENTIAL INFORMATION THAT COULD CAUSE HARM TO RESEARCH SUBJECTS, THE PI, OR THE UNIVERSITY.



Data Use contract language

SOMETIMES THERE IS NOT A SEPARATE AGREEMENT FOR DATA USE. THE LANGUAGE MAY BE INCLUDED WITHIN YOUR CONTRACT OR AN AMENDMENT. DATA USE CONTRACT LANGUAGE REQUIRES THE SAME SCRUTINY AS DATA USE AGREEMENTS

WILL MY PROJECT NEED REVIEWED?

IF THERE IS A TRANSFER OF HUMAN SUBJECT DATA BETWEEN ENTITIES, IT WILL NEED REVIEWED.

IF YOUR PROJECT INVOLVES, PHI (PRIVATE HEALTH INFORMATION) OR PII (PERSONALLY IDENTIFIABLE INFORMATION), IT WILL NEED TO BE REVIEWED.

IF A DUA OR A CONTRACT WITH DATA USE LANGUAGE IS RECEIVED, YOUR PROJECT WILL NEED TO BE REVIEWED.

-INCLUDES LIMITED DATA SETS.

A DUA IS NOT TYPICALLY REQUIRED WHEN DATA IS AVAILABLE IN THE PUBLIC DOMAIN OR WHEN DATA EXCHANGE IS NOT SUBJECT TO RESTRICTIONS.

Exhibit A: Is data sharing permitted?



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What counts as PHI?

PHI IS ANY PERSONAL HEALTH INFORMATION THAT CAN POTENTIALLY IDENTIFY AN INDIVIDUAL THAT WAS CREATED, USED, OR DISCLOSED IN THE COURSE OF PROVIDING HEALTHCARE SERVICES, WHETHER IT WAS A DIAGNOSIS, TREATMENT OR RESEARCH, SUCH AS:

- NAMES
- ALL ELEMENTS OF DATES, EXCEPT YEAR, DIRECTLY RELATED TO AN INDIVIDUAL INCLUDING BIRTHDATE, ADMISSION DATE, DISCHARGE DATE, ETC.
- GEOGRAPHIC DATA SMALLER THAN A STATE, SUCH AS ZIP CODES
- TELEPHONE AND FAX NUMBERS
- SOCIAL SECURITY NUMBERS
- EMAIL ADDRESSES
- MEDICAL RECORD NUMBERS
- ACCOUNT NUMBERS
- HEALTH PLAN BENEFICIARY NUMBERS
- CERTIFICATE/LICENSE NUMBERS
- VEHICLE IDENTIFIERS AND SERIAL NUMBERS INCLUDING LICENSE PLATES
- WEB URLS
- DEVICE IDENTIFIERS AND SERIAL NUMBERS
- INTERNET PROTOCOL ADDRESSES, (IP ADDRESSES)
- FULL FACE PHOTOS AND COMPARABLE IMAGES
- BIOMETRIC IDENTIFIERS (I.E. RETINAL SCAN, FINGERPRINTS)
- ANY UNIQUE IDENTIFYING NUMBER OR CODE

THE RULE OF THUMB IS THAT IF ANY OF THE INFORMATION IS PERSONALLY RECOGNIZABLE TO THE PATIENT OR IF IT WAS UTILIZED OR DISCOVERED DURING THE COURSE OF A HEALTHCARE SERVICE, IT IS CONSIDERED TO BE PHI.

What counts as PII?



PII IS ANY INFORMATION THAT CAN BE USED TO IDENTIFY, CONTACT, OR LOCATE A PATIENT, SUCH AS:

- FULL NAME
- MAIDEN NAME OR MOTHER'S MAIDEN NAME
- ALIASES
- DATE OF BIRTH
- ADDRESSES
- PHONE NUMBERS
- EMAIL ADDRESS
- DRIVER'S LICENSE OR STATE ID INFORMATION
- PASSPORT NUMBERS
- SOCIAL SECURITY NUMBERS
- CREDIT CARD NUMBERS
- BANK ACCOUNT NUMBERS
- IP ADDRESSES
- DEVICE IDS
- GPS LOCATION DATA
- PHOTOS
- FINGERPRINTS
- EMPLOYMENT OR EDUCATIONAL RECORDS

What is NOT considered PHI/PII?

IDENTIFIABLE INFORMATION BY ITSELF IS NOT PII OR PHI. TO CONSTITUTE PII/PHI, AND THEREBY BE SUBJECT TO REGULATION BY HIPAA, IT MUST RELATE TO HEALTH STATUS. IT MUST BE CREATED, COLLECTED, TRANSMITTED, OR MAINTAINED BY A COVERED ENTITY WITH RESPECT TO PROVISION OF HEALTHCARE, PAYMENT OF HEALTHCARE, OR USE IN HEALTHCARE OPERATIONS ACTIVITIES, INCLUDING RESEARCH

IF THE DATA CAN BE USED TO PERSONALLY IDENTIFY AN INDIVIDUAL *AND* THAT INFORMATION WILL BE USED BY A COVERED ENTITY, THEN THAT INFORMATION IS CONSIDERED PHI/PII AND IS SUBJECT TO HIPAA. IF YOU HAVE NO PLANS ON SHARING THIS DATA WITH A COVERED ENTITY, IT MAY NOT REQUIRE FURTHER REVIEW.

How do we determine the risks?

A NUMBER OF FACTORS CAN BE USED TO IDENTIFY THE LEVEL OF RISK (I.E., LOW HARM, SIGNIFICANT HARM) BASED UPON HOW MUCH HARM A BREACH IN EACH CATEGORY CAN CAUSE. THE NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY RECOMMENDS WE CONSIDER THE FOLLOWING FACTORS WHEN DETERMINING WHAT CATEGORY TO PUT DATA INTO:

- **IDENTIFIABILITY:** IS IT EASY TO UNIQUELY IDENTIFY THE INDIVIDUAL?
- **QUANTITY OF PHI/PII:** HOW MANY IDENTITIES COULD BE COMPROMISED BY A BREACH?
- **QUANTITY OF HARM:** HOW MUCH HARM COULD THE DATA CAUSE, IF BREACHED? A PHONE NUMBER IS LESS SENSITIVE THAN A CREDIT CARD OR SOCIAL SECURITY NUMBER, FOR EXAMPLE.
- **CONTEXT OF USE:** DOES THE WAY THE INFORMATION IS USED AFFECT ITS IMPACT?
- **ACCESS TO AND LOCATION OF PHI/PII:** THE PERSONALLY IDENTIFIABLE INFORMATION HIPAA GOVERNS IS OFTEN STORED, TRANSPORTED, AND PROCESSED BY THIRD PARTY IT SERVICES, ACCESSED OFFSITE BY MEDICAL PROFESSIONALS WHO AREN'T EMPLOYEES OF THE ORGANIZATION AND PROCESSED BY A VARIETY OF BUSINESS ASSOCIATES. THIS CREATES RISKS THAT WOULDN'T BE PRESENT, FOR EXAMPLE, IF THE PHI/PII WERE LOCKED IN A VAULT, AND COULD ONLY BE ACCESSED BY ONE PERSON. REMOTE WORK BY USF EMPLOYEES MAY ALSO FALL UNDER THIS SCRUTINY.



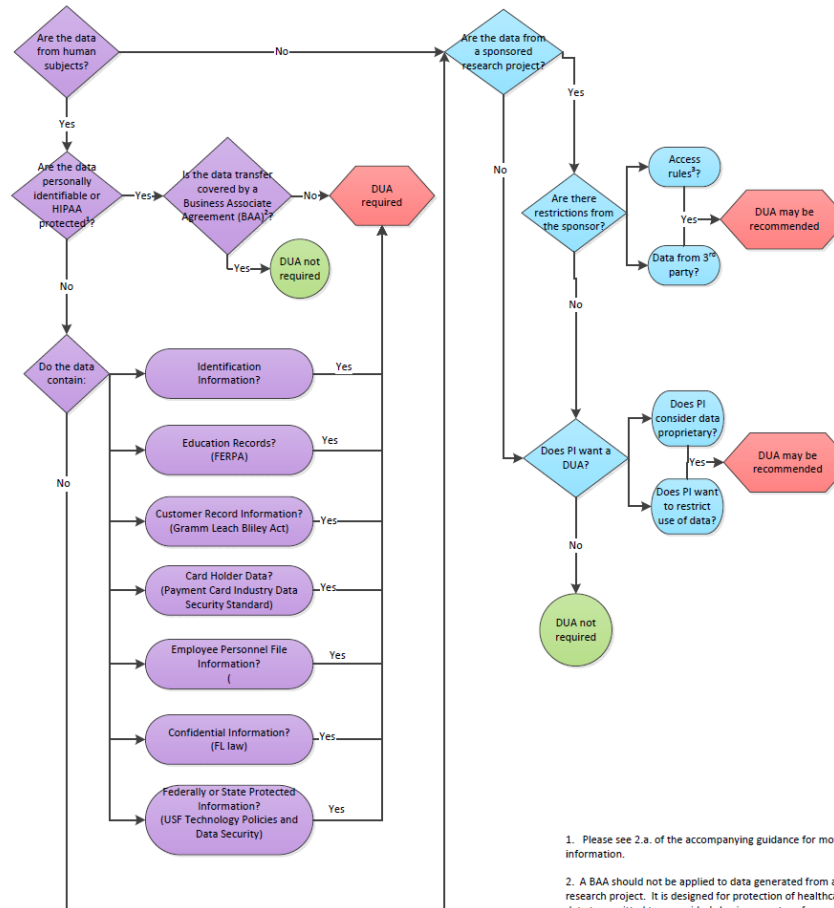
USF PROCESS FOR DATA USE REVIEW

FACULTY SHOULD SEE THEIR UNIT RESEARCH ADMINISTRATOR TO BEGIN THE PROCESS

THE URA WILL COMPLETE AS MUCH OF THE DATA USE INTAKE FORM AS POSSIBLE FOR THE ADMINISTRATIVE QUESTIONS THEN SEND IT TO THE PI OR STUDY STAFF TO COMPLETE THE PROGRAMMATIC PORTION

ONCE COMPLETE THE URA WILL SUBMIT THE INTAKE FORM TO BEGIN THE REVIEW. THE REVIEW INCLUDES REPRESENTATION FROM SPONSORED RESEARCH, IT, LEGAL, AND RESEARCH INTEGRITY COMPLIANCE.

Exhibit B: Is a Data Use Agreement Needed or Recommended?



1. Please see 2.a. of the accompanying guidance for more information.

2. A BAA should not be applied to data generated from a research project. It is designed for protection of healthcare data transmitted to a provider's business partner for execution of business responsibilities.

3. Examples of access rules could be the rules governing a public database where PI obtained data, or limitations present in the funding agreement that supported the collection of the data. Contact DSP to learn more.

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Data Use Intake Form-PI or URA completes this section

UNIVERSITY OF SOUTH FLORIDA DATA USE INTAKE WORKSHEET

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
PI First Name	PI Last Name	URA First Name	URA Last Name
PI email: <input type="text"/>		URA email: <input type="text"/>	
<input type="text"/>	<input type="text"/>	<input type="text"/>	
College	Department	Associated Project ID (if applicable)	
Review requested for: Data Use Agreement (DUA) <input type="checkbox"/>		Research Agreement with DUA Article <input type="checkbox"/>	
Is the data use related to primary or subcontract project? Yes <input type="checkbox"/> No <input type="checkbox"/> (provide supporting documents)			
Request is for: New/Initial <input type="checkbox"/> Renewal <input type="checkbox"/> Extension/Amendment <input type="checkbox"/>			
<input type="text"/>			
Project Title			
<input type="text"/>			
Contracting Entity/Agency			
<input type="text"/>			
Agency Point of Contact (name, phone, email, website)			

Individuals (besides PI and URA) who should receive notifications about this data use review:

Name	Email Address	Name	Email Address

Will USF provide data to another entity? Yes No (If yes, include details under "Shared")

Will the sponsor provide a system or technology as part of this agreement? Yes No Unsure

Will the data related to this agreement/contract be combined or otherwise linked to data received under other agreements? Yes (please provide other documents) No

Does this project involve humans subjects? Yes No Unsure Approved IRB#

Does this project include protected health information (PHI) or other HIPAA-related data? Yes No

Does this project involve animals? Yes No Unsure Approved IACUC#

Does this project require compliance with regulations, such as ITAR, EAR, or FAR clauses? Yes No Unsure

If YES or Unsure, send this completed worksheet with agreement/award documents, IRB approval, etc. as a separate attachment to cwalters@usf.edu

If NO, send this completed Worksheet with DUA and associated award documents, IRB approval, etc. as a separate attachment to datause@usf.edu

Are you collaborating with any non-USF persons or other institutions on this project? Yes No

Are you purchasing a computer device solely for this project? Yes No

If Yes, will the device be purchased with university resources? or with personal resources?

If purchased with university resources, does the device require encryption? Yes No Unsure

Does this project involve the creation of intellectual property? Yes No Unsure

Provide a brief summary of the project:

The PI or coPI should complete this section. Be as thorough as possible

Team and office information should be completed by PI or URA

Project team information (attach sheet if additional space is needed):

Name	Role	Type of machine	Machine Name	Service Tag	Encrypted?	Bldg/Room
		Desktop			Yes	
		Desktop			Yes	
		Desktop			Yes	
		Desktop			Yes	
		Desktop			Yes	

Machine Name Example

C068261

Service Tag Example

Service Tag: FK6QDW2
 Expires: 3/31/2018
 Mfg. Date: 2/1/2018

Project Workspaces:

For the rooms listed above, do they have (attach sheet if additional space is needed):

Bldg/Room	Room Access	Privacy Concerns	Type of Space
	Door Key	No concerns	Private office
	Door Key	No concerns	Private office
	Door Key	No concerns	Private office
	Door Key	No concerns	Private office
	Door Key	No concerns	Private office

For this DUA, please provide details on how the data will be:

- Collected from the original source:

- Received by the PI/USF:

- Processed/Used by the research team:


- Shared/Reported/Disseminated:

- Stored (include all safety measures to protect data):

- Retained (how long will the data be kept):

- Disposed

Additional Comments/Notes:



THE PI OR COPI SHOULD COMPLETE THIS SECTION. THEY SHOULD DISCLOSE AS MUCH DETAIL AS POSSIBLE FOR EACH QUESTION SO THAT THE REVIEW COMMITTEE CAN PROVIDE A THOROUGH REVIEW WITHOUT HAVING TO ASK SUPPLEMENTAL QUESTIONS DUE TO MISSING INFORMATION. MISSING INFORMATION CAUSES DELAYS IN REVIEW AND EXECUTION OF DUAS AND CONTRACTS.



What does the review entail?

USF WILL DETERMINE, BASED ON THE DATA USE AGREEMENT AND INTAKE FORM, IF THE RESEARCH THAT IS BEING PROPOSED FALLS UNDER HIPAA REGULATIONS FOR PRIVACY. THE REVIEW WILL ALSO DETERMINE IF THERE IS ANY RISK FOR DATA BREACH AND TAKE APPROPRIATE MEASURES TO ENSURE THAT DATA IS PROTECTED, USED APPROPRIATELY, STORED SAFELY, TRANSMITTED/DISSEMINATED WITH PROTECTIONS IN PLACE, AND DISPOSED OF AS REQUIRED BY LAW/SPONSOR GUIDELINES.

How do we keep data secure?

- PURGING UNNECESSARY IDENTIFYING INFO FROM RECORDS.
- DE-IDENTIFYING (ANONYMIZING) DATA AND FEEDBACK SO THAT IT CANNOT BE IDENTIFIED.
- IMPLEMENT ACCESS CONTROL MEASURES. SENSITIVE INFORMATION SHOULD ONLY BE ACCESSIBLE BY PEOPLE WHO ABSOLUTELY NEED IT TO DO THEIR JOBS.
- ENCRYPT ALL SENSITIVE INFORMATION.
- STORE DATA IN A SECURE LOCATION, SUCH AS AN ENCRYPTED SERVER.

Resources

[HTTPS://PRIVACYRULEANDRESEARCH.NIH.GOV/PDF/HIPAA_BOOKLET_4-14-2003.PDF](https://privacyruleandresearch.nih.gov/pdf/HIPAA_BOOKLET_4-14-2003.pdf)

[HTTPS://WWW.HHS.GOV/SITES/DEFAULT/FILES/HIPAA-SIMPLIFICATION-201303.PDF](https://www.hhs.gov/sites/default/files/HIPAA-Simplification-201303.pdf)

[HTTPS://WWW.USF.EDU/RESEARCH-INNOVATION/SR/DOCUMENTS/DATA-USE-AGREEMENT-INTAKE-FORM.PDF](https://www.usf.edu/research-innovation/sr/documents/data-use-agreement-intake-form.pdf)