Data Use Language in DUAs and contracts

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



Data Use contract language

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.

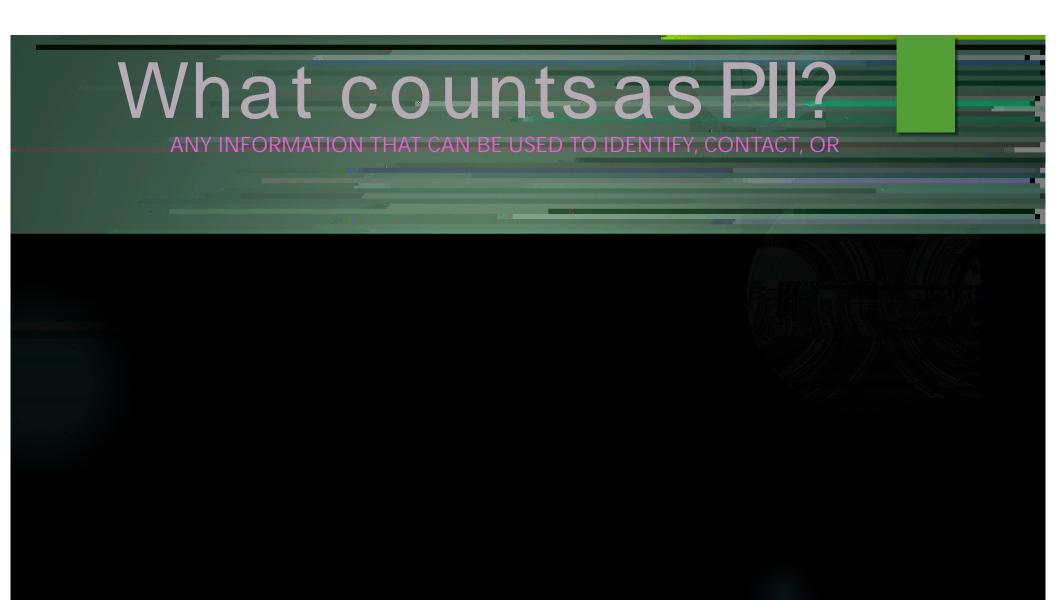
-INCLUDES LIMITED DATA SETS.

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











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 BEG IN THE REVIEW. THE REVIEW INCLUDES REPRESENTATION FROM SPONSORED RESEARCH, IT, LEGAL, AND RESEARCH INTEGRITY COMPLIANCE.



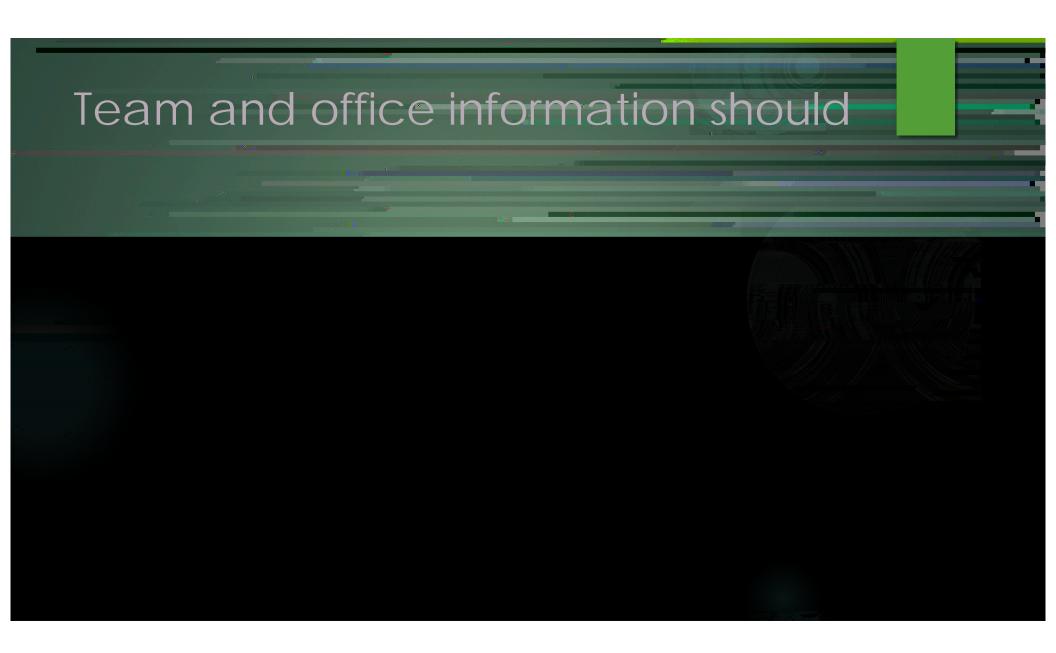


Data Use Intake Form-PI or URA completes this section

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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 THE THERE IS ANY RISK FOR DATA BREACH AND TAKE APPROPRIATE MEASURES TO ENSURE THAT DATA IS PROTECTED, USED APPROPRIATELY, STO RED SAFELY, TRANSMITTED/ DISSEMINATED WITH PROTECTIONS IN PLACE, AND DISPOSED OF AS REQUIRED BY LAW/ SPONSOR GUIDELINES.





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