Sponsored Projects Office (SPO)

Data Use Agreements (DUAs)

Agenda

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- Common Definitions
- Why is a DUA is needed?
- When is a DUA needed?
- DUA Process
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What is a DUA?

- A Data Use Agreement (DUA) is a contractual agreement, between the “provider” of the data and the “recipient” of the data, used for the transfer of non-public data, or data that is subject to restrictions on its use (i.e. HIPAA and/or Security Requirements).
- DUAs typically address issues around limitations on use, liability for harm arising from use of the data, publication, and how data will be exchanged, accessed, stored, used, and protected.

Definitions

- HIPAA – acronym for the Health Insurance Portability and Accountability Act that was passed by Congress in 1996. HIPAA requires the following:
  - Protection and confidential handling of Protected Health Information (PHI)
  - Assurance that a patient's health information cannot be used or shared without the patient's written consent
  - Compliance by all "Covered Entities," defined as any: health plan, healthcare clearinghouse, or healthcare provider
  - Reduction of health care fraud and abuse and potential unwarranted release of patient data
- PHI – acronym for Protected Health Information. PHI is information that is created or received by a health care provider regarding the physical or mental health condition of an individual, the provisioning of health care to the individual, or any payment information for the individual's receipt of health care.
- Under HIPAA, there are 18 distinct identifiers that constitute PHI

The 18 HIPAA Identifiers

- Names
- Geographic subdivisions smaller than a state (e.g. street address, city and ZIP code)
- All dates that are related to individual (e.g. date of birth, admission)
- Telephone numbers
- Fax numbers
- Email 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 locators (URLs)
- IP address numbers
- Biometric identifiers such as fingerprints and voice prints
- Full-face photographic images
- Other unique identifying numbers, characteristics or codes

Definitions Continued

- LDS – acronym for a Limited Data Set. A "limited data set" is a subset of the 18 patient identifiers defined in the HIPAA Privacy Regulations. In order for the data to be classified as a LDS, the following information pertaining to patient, his or her employer, relatives and household members must be removed:
  - Name, address, and phone number
  - Medical identification or account number
  - Health plan or insurance numbers
  - Social Security numbers
  - Web and IP addresses
  - Vehicle identification information such as license plate numbers
  - Serial numbers or identifiers from devices
  - Fingerprint records or voice records
  - Facial photographs

*A limited data set may include the following: dates such as admission, discharge, service, DOB, DOD; city, state, five digit or more zip code; and ages in years, months or days or hours

Definitions Continued

- De-identified data – data that has been stripped of all “direct identifiers” or all information that can be used to identify the patient from whose medical record the health information was derived. A de-identified data set does not contain any of the 18 HIPAA identifiers.

HIPAA Requirements

- HIPAA requires that the information be appropriately secured at all times (in-transit and at rest).
- The data must be secured against any inappropriate or unauthorized use/access or further disclosures (i.e. system hacks, data theft)
- HIPAA requires that any unauthorized use/access be reported to the data provider within strict timelines. This is due to HIPAA's timing requirements for notifying patients of any breach related to their PHI.
- For de-identified data (data that cannot be used to connect information with a person's identity), the recipient must not try to identify the patients and, if the data is coded, must not access that code.

Why is a DUA Needed?

- UNM Health Sciences and the Principal Investigator (PI) have a responsibility to appropriately safeguard all data that we collect, store, and share with any third party.
- A DUA ensures that appropriate restrictions on the use of data are maintained.
- A DUA protects the PI and UNM Health Sciences from any liability or loss arising from a recipient's use of UNM Health Sciences data.

When is a DUA needed?

- A Data Use Agreement (DUA) is often required for any incoming or outgoing data related to human research.
- A DUA for non-human subject data transfers might be required and is initiated by a PI creating a Click record after receiving a non-human subject data determination from the Institutional Review Board (IRB).
  - If you are unsure how to create a Click record or don't have a login account, reach out to HSC-PreAward@salud.unm.edu for more information on the appropriate training.
- In order to determine if a DUA or another type of agreement is required, the IRB and SPO may ask a series of questions. Occasionally, a DUA will not be required but another type of collaboration agreement will.

Is a DUA Needed? Scenario 1

- UNM Health Sciences PI collaborates on a project with an investigator from University X. UNM Health Sciences will receive de-identified data from University X. Is a DUA needed?
  - YES! A DUA is needed between UNM Health Sciences (recipient) and University X (provider) for the de-identified data.

Is a DUA Needed? Scenario 2

- UNM Health Sciences PI collaborates on a project with an investigator from University X. UNM Health Sciences PI arranges University X access to the UNM Health Sciences REDCap system for data entry/management of University X participants. UNM Health Sciences will have access to de-identified data uploaded by University X to the REDCap system. Is a DUA needed?
  - YES! A DUA is needed since University X (provider) is allowing UNM Health Sciences (recipient) to access their de-identified data.

Is a DUA Needed? Scenario 3

- UNM Health Sciences PI collaborates on a subaward with an investigator from University X (outgoing $'s to University X). The subaward issued to University X includes data language for de-identified data to be received by UNM Health Sciences. Is a DUA needed?
  - No. A separate DUA contract is not needed since the subaward agreement includes reference to the transfer of the de-identified data and how it will be received. The DUA is effectively 'built into' the subaward contract.

Is a DUA Needed? Scenario 4

- UNM Health Sciences PI collaborates with University X on a project that will only require the UNM Health Sciences PI and study team to provide their participants with a link to an online anonymous survey hosted on University X's database. Is a DUA needed?
  - No. Since there is no UNM Health Sciences data that is being shared, there is no DUA needed. The participants are directly entering their information into University X's database.

DUA Process

- DUAs are initiated through SPO, with the PI completing the DUA Request Form and submitting it through the Click Agreements systems.
  - If you are unsure how to create a Click record or don't have a login account, reach out to HSC-PreAward@salud.unm.edu for more information on the appropriate training.
- SPO will draft and execute the DUA, after review and approval by the HSC Privacy and IT Security Offices.
- IRB Approval is not needed for execution of the DUA. However, data CANNOT be shared until the IRB protocol has been approved.
- If the IRB protocol does not match the executed DUA, IRB will work with the PI to modify the protocol to align with the DUA.

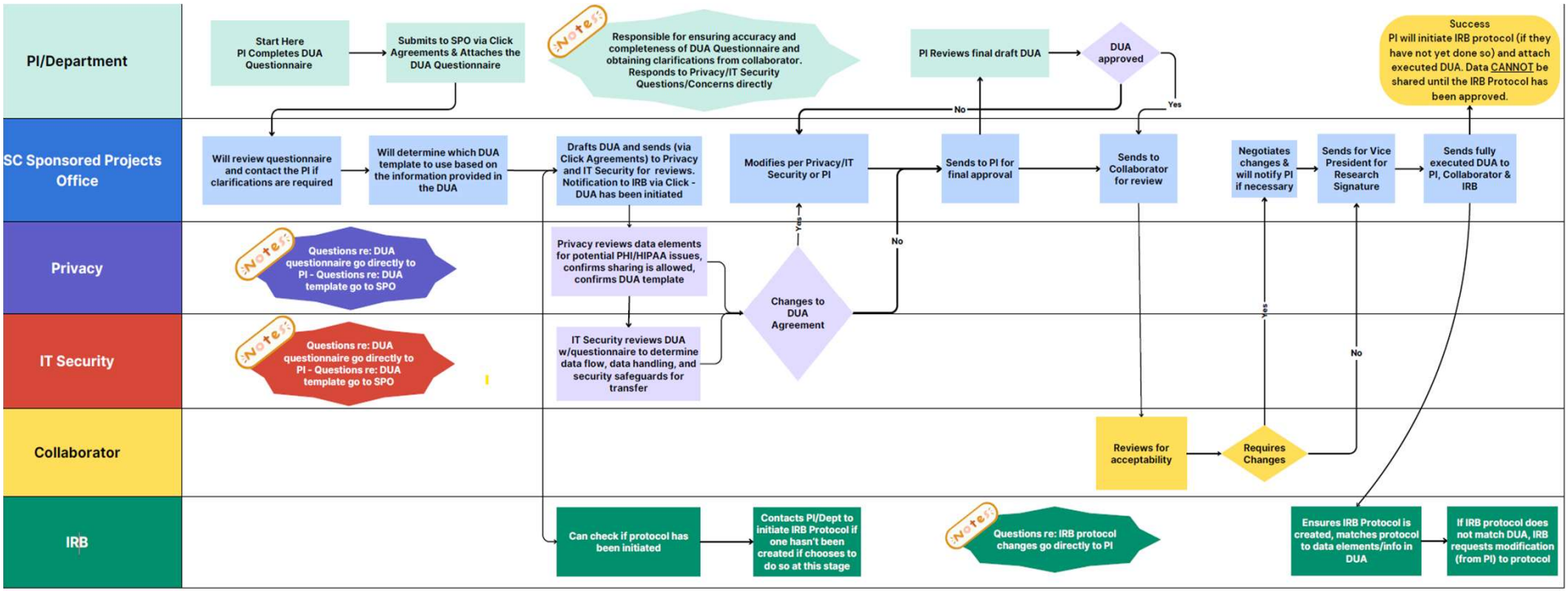
DUA Process Continued

- SPO offers various DUA templates tailored to the classification of the data that is being exchanged. These includes:
  - Templates approved by the Office of University Counsel PHI, Limited and De-identified data
  - Federal Demonstration Partnership (FDP) templates commonly used by many universities and research institutions
  - For incoming data, collaborators may also provide their own templates
- Sometimes, a separate DUA contract isn't needed if the data transfer is covered by another agreement detailing the data use requirements (e.g., Clinical Trial Agreements, Research Collaboration Agreements, or Subawards).

DUA Process Continued

- DUAs REQUIRE final approval from our Institutionally Authorized Signatory, which is Vice President of Research. Your SPO Specialist will route the DUA to the Vice President of Research when the contract is ready for final execution.

DUA Process Flowchart



DUA Request Form

DATA USE AGREEMENT REQUEST FORM

For all Data Use Agreements (DUAs), please send this completed form, along with any supplementing documents, via Click Agreements (instructions provided) to HSC Sponsored Projects. This form may be used for multiple DUA's under one Project BUT you must provide all collaborator contact information and data elements for each collaborator, however, a separate Click record will need to be initiated for each DUA under this project._

Please note: All information stated in this form must be congruently stated in your IRB protocol if human subject research.

1. Please complete the table below:

HSC Principal Investigator	
Name	
E-mail	
Project title	
Sponsored/ Project Award #:	
HSC PI Proxy	
Name:	
Email/Phone:	
External Party managing the DUA	
Name	
Type	◯ industry/company ◯ academic/research institution ◯ government agency ◯ other ☐ Check here if external party is a

Department contact that can assist with the DUA

Ensure that all questions are thoroughly answered!

Refer to the DUA Request Form Reference Guide for assistance in completing the information.

DUA Request Form Continued

Collaborator's Sponsored Projects contact information

External Party managing the DUA	
Name	
Type	◯ industry/company ◯ academic/research institution ◯ government agency ◯ other ☐ Check here if external party is a foreign entity
External Party Contact Information Name: E-mail: Phone:	

If there is more than one external party requiring a DUA for this project, please add other external parties. Please include the following for each additional external party:

Organization	Contact Name	Email/Phone	PI Full Name

Include Collaborator's PI information. Use multiple lines for multiple collaborators and complete all information for each.

DUA Request Form Continued

Provide a summary of the project including how the recipient will use the data.

2. Please provide a short description of the project (limit 250 words)

3. Is the data incoming, outgoing, or will it be shared both ways?

- ◯ Incoming (an external party will be sharing the data with UNM HSC)
- ◯ Outgoing (UNM HSC will share data with an external party)
- ◯ Both/Multidirectional with other institutions

4. Describe how the data will be securely transmitted/shared with another party below:

a. If using a database/data repository managed by another party, please include details about the system such as the URL for the site and the details for who will manage security, maintenance, and access controls for the site. Include institution and contact name.

b. If data is received/sent out using an HSC-managed system, please choose from the approved list below:

i. approved list of HSC solutions for data transfer:
   1. HSC's Secure File Transfer System (SFTP)
   2. HSC's REDCap
   3. UNM's Qualtrics (non-clinical data)

ii. if none of the above is an option, describe the plans for receiving, sending out, or accessing data. Consulting with the ISO on options is suggested. Contact ISO at: HSC-ISO@salud.unm.edu. Entering an IT Service request ticket for requesting any of the above services is also available.

The preferred data transfer methods are through HSC SFTP or HSC REDCap. If data is shared via an externally managed web portal, include the website link. For other methods, contact IT Security for assistance: HSC-ISO@salud.unm.edu

For human subject data, provide approved IRB protocol number. The DUA can be negotiated alongside the IRB review, but data transfer requires an approved IRB protocol.

5. Is this human subjects research data? If yes, please provide the IRB protocol number if one exists.

◯ Yes – IRB # _____ ◯ Not applicable ◯ Pending

DUA Request Form Continued

Indicate the type of data to be shared. Refer to our DUA Request Form Reference Guide or contact the Privacy Office for assistance: HSC-Privacy@salud.unm.edu

6. If this is human subjects data, select which of the following best describes the type of data. Check all that apply. Please see the DUA reference guide for definitions/examples.

- [ ] De-identified human subjects
- [ ] Limited Data Set
- [ ] personally identifiable information (PII)
- [ ] Protected Health Information(PHI)
- [ ] other, please explain

7. If this is human subject data, will the data be **shared with the external parties** include any of the following identifiers? (check all that apply; continue on the next page)

- [ ] Names
- [ ] Any geocodes that identify an individual household such as a street address or Post Office Box Number
- [ ] Telephone number
- [ ] Fax numbers
- [ ] Electronic mail (email) addresses
- [ ] Social Security numbers
- [ ] Health plan beneficiary identifiers
- [ ] Account numbers
- [ ] Certificate/license numbers
- [ ] Vehicle identifiers and serial numbers, including license plate numbers
- [ ] Medical device identifiers and serial numbers
- [ ] Web universal resource locators (URL)
- [ ] Internet Protocol (IP) address numbers

DUA Request Form Continued

List collaborators along with the data classification and description of the data to be shared.
Example: University X / de-identified / Incoming – Participant #, Vitals, Diagnosis

8. If human subject data, please describe data to be sent out (outgoing) and/or received (incoming) in the table below for each collaborator.

Collaborator (should match listed collaborators in Q1)	Data Classification of the Incoming/Outgoing Data (i.e. limited data set)	Describe Incoming Data	Describe Outgoing Data

9. Is the data that is going to be transferred/shared owned or partially owned by another party? Yes/No

   If Yes, please provide details:

10. Will you also be requiring a Material Transfer Request related to this DUA?

    Yes/No

    If yes, SPO will contact you with further directions.

11. Is the external entity a "covered entity" (HIPAA-covered entities include health care providers (i.e. hospitals, doctors, academic health centers), health plans, and clearinghouses): Yes/No

    Will UNM HSC have an honest broker as part of the data transfer??

    ◯ Yes ◯ No

Note that while a DUA can be executed before IRB approval, an executed MTA requires an approved IRB protocol.

Information Needed to Draft DUA

- Provide a detailed description of the data, including its classification (e.g., de-identified, limited data set, etc.) and the specific data elements to be transferred (e.g., patient names, MRI images, patient vitals).
- Describe the data flow, indicating whether it is incoming or outgoing, if a third-party honest broker is involved, and whether the study is multi-site or includes additional collaborators.
- Summarize how the data will be sent, accessed, and transferred, by whom, and which secure application will be used (e.g., REDCap). Include any relevant external URLs.
- Specify any restrictions or requirements on third party access and any unusual security measures required for the study.

Security and Institutional Requirements

- IT/Security review ensures appropriate safeguards and secure systems are in place.
- UNM Health Sciences IT Security's current requirement is that all incoming data be sent directly to Central/IT to be secured and then provide access to the PI in accordance with the DUA.
- The more information we have regarding the data flow, data classification, and any special or unique requirements, the faster the DUA can be finalized.

Who Does What?

Sponsored Projects Office (SPO)

- Reviews DUA Request Form to determine DUA template
- Communicates with PI / team to address any questions or concerns
- Drafts and forwards DUA templates to Privacy Office, Information Security Office, and PI for review
- Receives legal dept. approval, if applicable (e.g., template language concerns)
- Negotiates DUA with collaborating institution
- Obtains signatures
- Tracks DUAs in Click ERA

Privacy Office

- Reviews data share information in DUA Request Form (data elements reviewed for potential PHI / HIPAA issues)
- Confirms that proposed sharing of data is allowed under HIPAA Privacy Rule
- Determines / confirms appropriate DUA template, and that data elements are de-identified, limited data set, PHI or other
- Communicates with PI / team to address questions or concerns
- Advises SPO on other privacy standards that apply and language that needs to be included in DUA template
- Receives legal dept. approval, if applicable (e.g., data sharing concerns)

Information Security Office

- Reviews DUA Request Form information to determine data flow, proposed data handling requirements, and security safeguards for storage, transfer and sharing
- Ensures data transfers (sent or received) are secured by HSC Central IT in compliance with all applicable policies and procedures
- Ensures devices that store or share data have been secured in compliance with HSC IT standards
- Communicates with PI / team to address questions or concerns
- Advises SPO with special security needs and recommends modifications to the default DUA template (specific language covering unique security safeguards)

Human Research Protections Office (HRPO)

- Ensures IRB Protocol is created, and that data sharing information aligns with DUA
- If IRB protocol does not match DUA, IRB will work with the PI to modify the protocol

Who to Contact?

HSC Sponsored Projects Office (SPO)

Phone: 272-9383

Email: HSC-PreAward@salud.unm.edu

HSC Privacy Office (Privacy)

Phone: 272-1493

Email: HSC-Privacy@salud.unm.edu

Human Research Protections Office (IRB)

Phone: 272-1129

Email: HRPO@salud.unm.edu

HSC Information Security Office (IT)

Phone: 272-1694

Email: HSC-ISO@salud.unm.edu