DATA USE AGREEMENTS

HOW TO GUIDE AND BEST PRACTICES

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DUA – FAQ’S

• WHAT IS A DUA?
  • A DUA is a document used to effectuate the transfer and/or sharing of data between two or more entities. It can be titled a DUA (Data Use Agreement), DTUA (Data Transfer & Use Agreement), DAA (Data Access Agreement), and/or RCA (Research Collaboration Agreement).

• TYPES of Transfers
  • Outgoing Data – CWRU as Provider
  • Incoming Data – CWRU as Receiver
  • Reciprocal Data – CWRU is both a Provider and a Receiver
  • Accessing Data – CWRU is neither a Provider nor a Receiver in the traditional sense

• When Do I Need a DUA?
  • When CWRU is providing data to another party;
  • When CWRU is receiving data from another party who wants a DUA;
  • When CWRU is providing or receiving Human Subjects’ Research Data
  • Note: Anytime data is being transferred to or from CWRU, you should request a DUA consultation.
Data Use Agreement General Guidance

- It is STRONGLY recommended that DUA language/terms and conditions, be included in sponsored research agreements, including subcontracts, whenever possible.

- DUAs may require IRB approval and/or Data Security Plan approval.

- **General Categories of Data** *(more on this in a minute)*
  - Data not from a human subject
  - Data that is derived from a human being that is considered Not Human Subjects’ Data
    - The CWRU investigator is not engaged in the research
    - Cannot use the data to identify an individual
    - Examples: de-identified data, sequencing data
  - Data that is collected from human beings or as part of a human subjects’ research study
    - Data types: Protected Health Information (PHI), Personally Identifiable Information (PII), and/or Limited Data Set (LDS)
      - An approved IRB protocol will be required

- Requests are to be submitted through DUA Request form: DUA Request Form

- It is strongly recommended that faculty and staff consult the Data Use Agreement Guidance. This document contains all the questions and directions on how to answer each question.
TYPES OF DATA

PHI and PII

- PHI – Personal Health Information
  - This includes information provided in your medical records, conversations with our Drs and other health care providers, information about you in your health insurer’s system, medical billing information, and any other personal health information.

- PII – Personal Identifiable Information
  - This is information that permits the identity of an individual to whom the info applies to be reasonably inferred by either direct or indirect means.

LDS & DID

- LDS – Limited Data Set
  - This is information from which “facial” identifiers have been removed as it relates to an individual or his/her/their relatives, employers, or household members (think names, addresses, email, phone numbers, etc).

- DID – De-Identified Data
  - This is data that is devoid of any identifiers. When used alone or when combined with other data, it cannot identify an individual who is the subject of that information.
    - Coded DID is de-identified data that can be linked back to the individual.
TYPES OF DATA AID: PHI/PII

DEFINITIONS: PROTECTED HEALTH INFORMATION (PHI)

A. The HIPAA Privacy Rule provides federal protections for personal health information held by covered entities and gives patients an array of rights with respect to that information. At the same time, the Privacy Rule is balanced so that it permits the disclosure of personal health information needed for patient care and other important purposes.

1. Covered Entities include Health Plans, Most Health Care Providers, and Health Care Clearinghouse.

2. Protected information includes: information your Doctors, Nurses, and other health are providers put in your medical record; Conversations your Doctor has about your care and/or treatment with nurses and others; information about your in your health insurer’s computer system; Billing information about you at your clinic/healthcare providers office; and most other health information about you held by those who must follow these laws.

DEFINITIONS: PERSONAL IDENTIFIABLE INFORMATION (PII):

A. 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.

B. PII is information that directly identifies an individual (e.g., name, address, social security number or other identifying number or code, telephone number, email address, etc.) or (ii) by which an agency intends to identify specific individuals in conjunction with other data elements, i.e., indirect identification.

1. Additionally, information permitting the physical or online contacting of a specific individual is the same as personally identifiable information. This information can be maintained in either paper, electronic or other media.
TYPES OF DATA AID: LIMITED DATA SET

1. **DEFINITION: LIMITED DATA SET (LDS):**
   
   A "LIMITED DATA SET" is information from which "FACIAL" identifiers have been removed. Specifically, as it relates to the individual or his or her relatives, employers or household members.

   B. All the following identifiers must be removed in order for health information to be a "LIMITED DATA SET":
      
      1. Names;
      2. Street addresses (other than town, city, state and zip code);
      3. Telephone numbers;
      4. Fax numbers;
      5. E-mail addresses;
      6. Social Security numbers;
      7. Medical records numbers;
      8. Health plan beneficiary numbers;
      9. Account numbers;
      10. Certificate license numbers;
      11. Vehicle identifiers and serial numbers, including license plates;
      12. Device identifiers and serial numbers;
      13. URIs;
      14. IP address numbers;
      15. Biometric identifiers (including finger and voice prints);
      16. And full-face photos (or comparable images)

   C. The health information that may remain in the disclosed information includes:
      
      1. Dates such as admission, discharge, service, DOB, DOD; city, state, 5-digit zip code; and ages in years, months, days or hours
**TYPES OF DATA AID: DE-IDENTIFIED DATA**

**Definition: De-Identified Information (DID)**

A. The following identifiers of the individual and/or their relatives, employers, or household members must be removed:

1. Names; All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census: (A) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (B) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000; All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older; Telephone numbers; Fax numbers; Electronic mail 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 Resource Locators (URLs); Internet Protocol (IP) address numbers; Biometric identifiers, including finger and voice prints; Full face photographic images and any comparable images; and Any other unique identifying number, characteristic, or code; and

2. The covered entity does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information.
TYPES OF CWRU DUAS

STAND-ALONE DUAs

- **Standalone DUA’s** are NOT part of a Sponsored Research Agreement, Research Collaboration agreement, or other award.
  - These are typically issued when data is being transferred as part of an unfunded research project/collaboration or a funded project where data transfer was not contemplated upfront.

- **DUAs with Affiliate Institutions**
  - CCF, MetroHealth, & VA (currently)

- **Data Purchasing Agreements**

EMBEDDED DUAs

- **Embedded DUA’s** are part of an agreement — be it a SRA, RCA, Subaward, or other agreement where the transfer of data was contemplated upfront and therefore DUA terms and conditions are included in the agreement.
  - These are becoming more common and are the most efficient way to effectuate the transfer of data.
  - **Prime Research Agreements** — DUA provisions embedded in research agreements
  - **Subcontract Agreements** — FDP Attachment 7 in subawards or include DUA provisions in the agreement
OVERVIEW OF STAND-ALONE DUA PROCESS

INCOMING/OUTGOING/RECIPROCAL DATA

• (1) Prescreen the DUA Request Form Questions and Guidance: HTTPS://CASE.EDU/RESEARCH/SITES/CASE.EDU.RESEARCH/files/2022-01/DUA Request Form Questions and Guidance January 2022.PDF

• (2) Complete the DUA Request Form & Hit Submit to send to the ORA DUA Team: HTTPS://CWRU.AZ1.QUALTRICS.COM/JFE/FORM/SV_8DMBKN0XPABETQI

• (3) Complete any questions, forms, information that ORA DUA requests from you.

• (4) Once complete – the DUA must be signed by Joan Schenkel and by an Authorized Institutional Signatory Official from the providing organization.

NEXT STEPS…

• Be Patient!! Your request will be processed in a timely manner. Things that can hold up the process:
  • Needing IRB Approval
  • Not providing an accurate and complete description of the data you want to transfer or receive
  • Not completing the form in its entirety
  • Providing inaccurate information
  • Not providing/uploading the requested documentation
  • Lag time of other party
INTERNAL STAND-ALONE PROCESS

1. Principle Investigator or research staff member completes DUA Request Form utilizing Data Use Agreement Guidance.

2. DUA staff will review the form to assess:
   1. If CWRU is providing data, receiving data, providing and receiving data, purchasing data, or accessing data.
   2. Category of data: not from living humans, from humans, or from humans but considered not human subjects’ data.
   3. Regulatory requirements: IRB approval and/or data security plan approval.
   4. The most appropriate data use agreement template (when draft agreement not provided).
   5. What terms and conditions are required.

3. DUA staff will work with PI to complete a draft DUA. PI will be required to describe data, data storage, data transfer, as well as confirm they understand and will adhere to terms and conditions of agreement.

4. PI will send the completed DUA form to cwru-dua@case.edu.

5. DUA staff will review the returned draft agreement and negotiate terms and conditions with the other party.

6. Once a mutually acceptable agreement has been drafted, DUA staff will execute the agreement.

   • Please Note: DUA’s may only be signed by authorized institutional officials.
STAND-ALONE TEMPLATES: FDP

FDP Templates

• FDP (Federal Demonstration Partnership) members have agreed to use a standardized non-negotiable template to effectuate data transfer between member organizations
  • Templates include: One-Way Sharing, Reciprocal Sharing, and Multi-Institutional Sharing
  • You will be sent the template to complete with instructions

• TIP: Complete the DATA DESCRIPTION with detailed specificity
• TIP: Complete the forms in their entirety
STAND-ALONE TEMPLATE: CLEVELAND CLINIC

Currently available for De-Identified Data & Limited Data Sets.

**Processes for De-identified and LDS Data Transfers:**

**CWRU Providing to CCF**
- CWRU Principal Investigator (PI) or Department Administrator (DA) completes CWRU DUA Request Form.
- CWRU DUA Team reviews and approves.
- CWRU DUA Team completes CCF Addendum.
- CWRU will email CCF PI to route to their DA for submission to legal.
  - NOTE: All IRB’s must be in place prior to CCF signing off.
- CCF DA will submit to a DUA Request, along with the provided Addendum to CCF.
- CCF will review and return any requested changes in redline, or, if approved, sending a partially executed (PE) doc to CWRU-DUA@CASE.EDU.
- CWRU will sign and return fully executed (FE) doc to the CCF DA and assigned CCF Paralegal.

**CCF Providing to CWRU**
- CCF DA completes CCF form.
  - CWRU PI completes CWRU form.
- CCF processes – reviews and approves.
  - CWRU DUA Team will review CWRU PI submission.
- CCF will send the Addendum to CWRU-DUA@CASE.EDU.
- CWRU DUA Team will review, return any requested changes in redline, or, if approved, return a PE doc to the CCF DA and assigned CCF Paralegal.
- CCF will sign and return a FE doc to CWRU-DUA@CASE.EDU.

**Reciprocal DUA Requests**
Will follow the same procedure as CWRU provides to CCF, absent any other agreement between CCF Paralegals and CWRU DUA Team.

*Note: VA and MetroHealth Processes coming soon!!*
EMBEDDED SUBCONTRACT PROCESS

1. **Data Transfer Determination**
   
   • The SOM or OSPA Pre-Award staff will ask via EMT in SPARTA if data transfer is required as part of the subcontract.

2. **Data Transfer Terms and Conditions Workflow** *(Will be initiated if the department grant administrator indicates that data transfer is required for the subcontract.)*
   
   a. SOM or OSPA Pre-Award staff will EMT the grant administrator and PI directing them to complete the DUA request form.
      
      (i) **Note:** Grant administrators or PIs can start the data transfer approval process if they know data transfer is required for the project subcontract.
   
   b. DUA staff will review the **DUA Request form to determine the type of data to be transferred and what regulatory requirements are required** - ex: IRB approval and/or data security approval.
   
   c. DUA staff will work with the SOM or OSPA Pre-Award staff to review the terms and conditions specific to data transfer.
      
      (i) If required, PI will return description of data to **CWRU-DUA@CASE.EDU**
   
   d. DUA staff will confirm the data described matches the DUA Request Form Responses
   
   e. DUA staff will upload the completed data description as well as redlined terms with EMT confirming the DUA information is ready for review and inclusion in agreement.
1. **Data Transfer Determination**
   a. The SOM or OSPA Pre-Award staff will ask via EMT in SPARTA if data transfer is required as part of the subcontract.
      (i) Note: For incoming agreements if Attachment 7 is included in the FDP template, then data transfer is required.

2. **Attachment 7 Workflow** (Will be initiated if the department grant administrator indicates that data transfer is required for the subcontract.)
   a. SOM or OSPA Pre-Award staff will EMT the grant administrator and PI directing them to complete the DUA request form.
      (i) Note: Grant administrators or PIs can start the data transfer approval process if they know data transfer is required for the project subcontract.
   b. DUA staff will review the DUA Request form to determine the type of data to be transferred and what regulatory requirements are required: IRB approval and/or data security approval.
   c. DUA staff will send Attachment 7 to PI and ask them to complete Attachment 7 - Description of Data.
   d. PI will return the completed Attachment 7 to [CWRU-DUA@CASE.Edu](mailto:CWRU-DUA@CASE.Edu).
   e. DUA staff will confirm that the data described in Attachment 7 matches the DUA Request Form Responses.
   f. DUA staff will upload the completed Attachment 7 to the FP with EMT to all pertinent parties confirming the form has been approved and attached.
ADDITIONAL INFORMATION: WHAT DOCUMENTS/INFORMATION YOU MAY NEED TO SUBMIT YOUR REQUEST

- **Detailed Description** of the data {who, what, when, where, how, and why}
- **DUA Template**
  - If the provider has sent you a DUA to use, that will need to be uploaded
- **IRB Approval Letter, IRB Protocol Template, IRB Consent Forms**
  - **Non-Human Subjects’ data** does NOT need IRB approval
  - **Human Subjects’ Data** will need IRB review
  - **Whole genome sequence data** will need IRB review
- **Data Security Plan**
  - **Restricted or secured data** will need a higher level of security.
  - **Cal Frye and/or Mark Herron** can approve your DSP
COMING SOON!!

- **DUA Guidebook**
- **MetroHealth DUA Process & Templates**
- **Veteran’s Association Process & Templates**
- **Data Security Specialist**
- **DUA Assistant Director**
THANK YOU!

- **ORA DUA TEAM: CWRU-DUA@CASE.EDU**
- **Joan Schenkel, Associate Vice President of Research** ([jms114@case.edu](mailto:jms114@case.edu))
- **Meghan Schane-Rambert, Director of Contracts & Data Use Agreements** ([mxs1788@case.edu](mailto:mxs1788@case.edu))