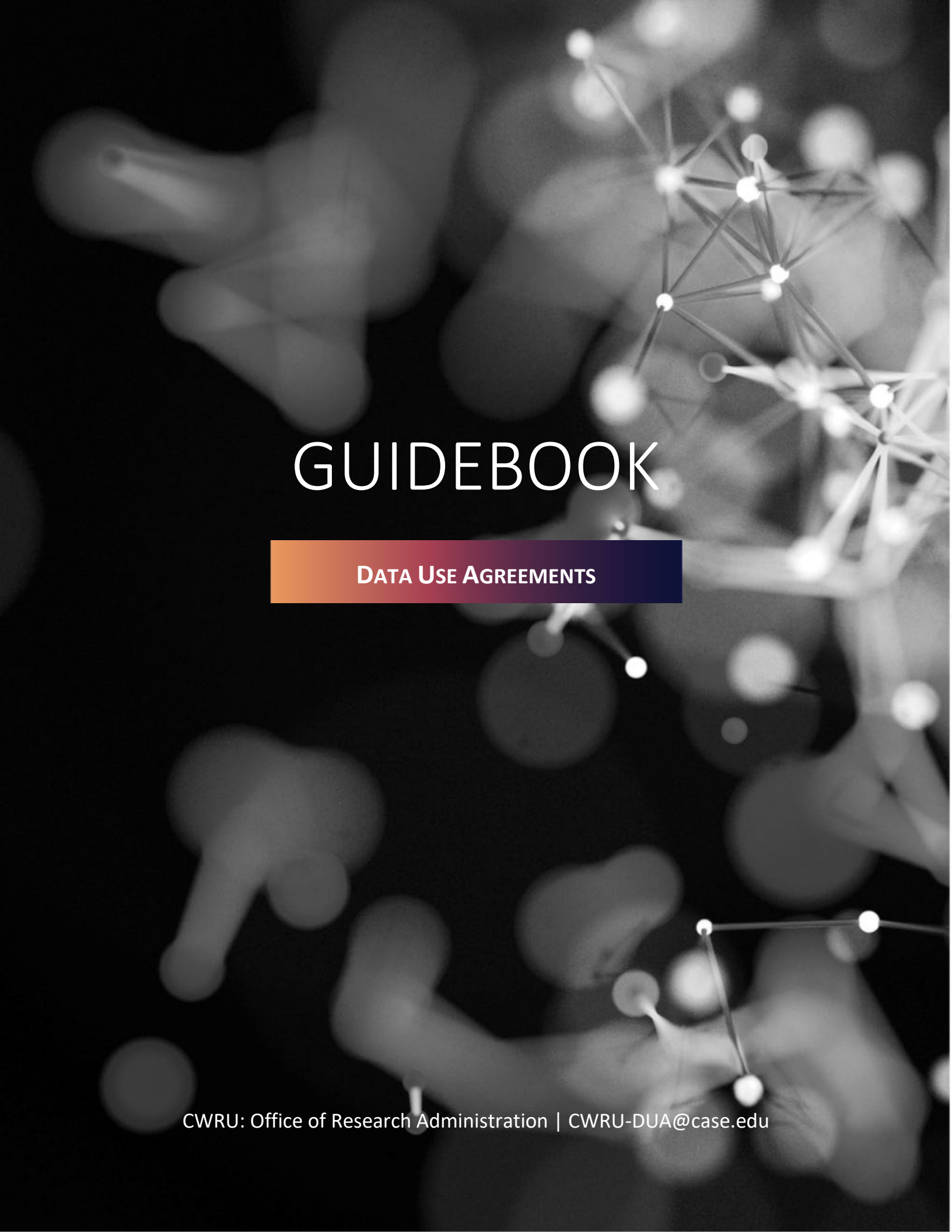
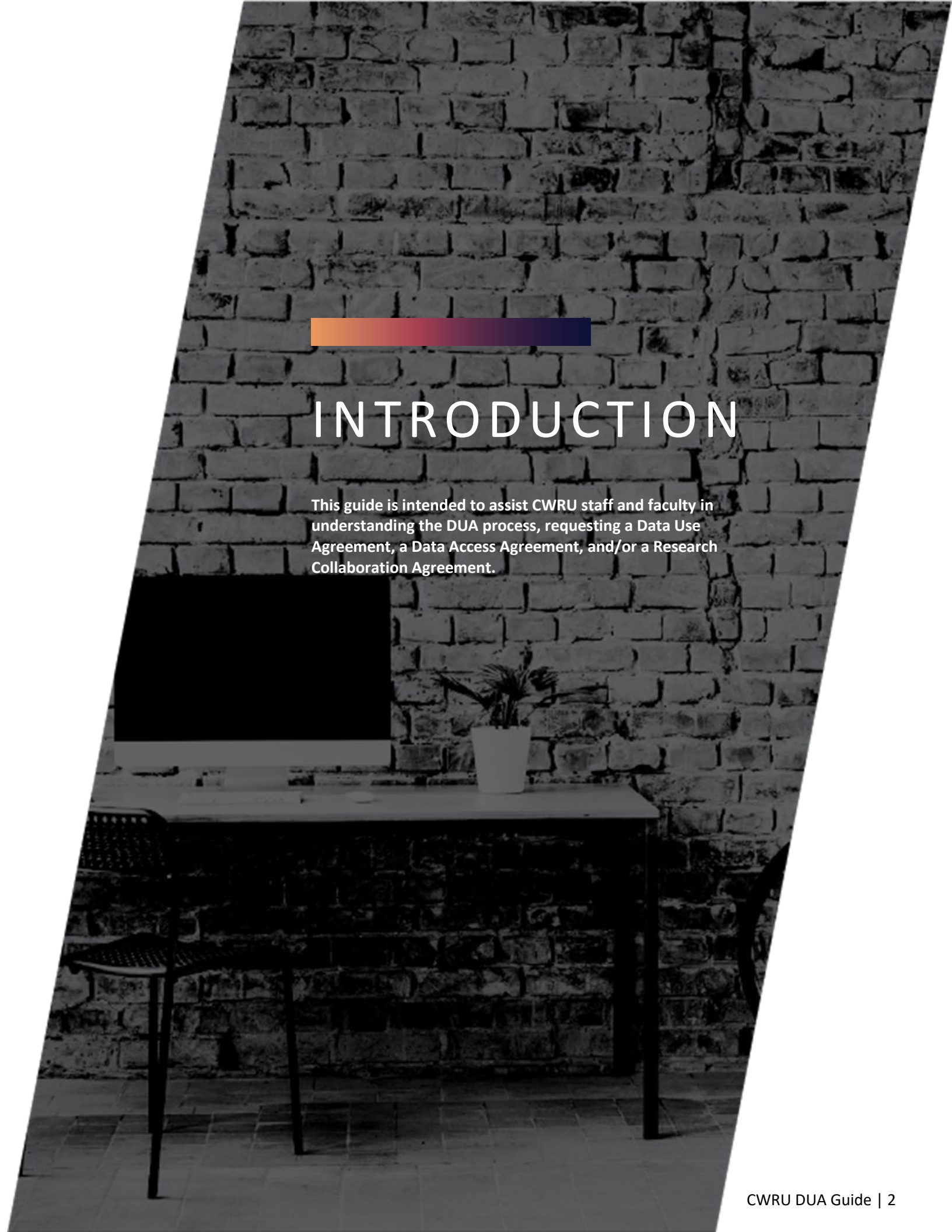


GUIDEBOOK

DATA USE AGREEMENTS

CWRU: Office of Research Administration | CWRU-DUA@case.edu



INTRODUCTION

This guide is intended to assist CWRU staff and faculty in understanding the DUA process, requesting a Data Use Agreement, a Data Access Agreement, and/or a Research Collaboration Agreement.

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ABOUT US

JOAN SCHENKEL, MS

ASSOCIATE VICE PRESIDENT FOR RESEARCH

Joan.schenkel@case.edu
(216) 368-4268

MEGHAN SCHANE-RAMBERT, ESQ

EXECUTIVE DIRECTOR OF CONTRACTS & DATA USE AGREEMENTS

Meghan.schane-rambert@case.edu
(216) 368-5092

MONICA BRADLEY

ASSISTANT DIRECTOR OF DATA USE AGREEMENTS

Monica.bradley@case.edu
(216) 368-5945

Office of Research Administration
10900 Euclid Ave.
Nord Hall 6th Floor
Cleveland, OH 44106

To Email the DUA Team, please use:
CWRU-DUA@case.edu

Institutional Review Board (IRB)
Kim Volarcik, CWRU IRB Director
Kimberly.volarcik@case.edu
(216) 368-4269

Incoming Data

- Data you are receiving from an outside provider.
- CWRU is the Receiver.

Outgoing Data

- Data you are sending or sharing with an outside receiver.
- CWRU is the Provider.

Reciprocal Sharing

- Data you are sending and receiving under the same agreement with the same outside party.
- Can also be part of An UNFUNDED research collaboration agreement.
- CWRU is both Provider and Receiver.

Accessing Data

- Data you are accessing through a portal.
- There is no actual physical transfer of the data.
- CWRU is neither Provider nor Receiver in the traditional sense.

DUA – FAQ'S

WHAT IS A DUA?

It is quite common for a research, service, or collaboration project to require the transfer of research data to, from, or between organizations. If you have data that is confidential, proprietary, or sensitive in some way, the party providing/sending the data will often require the receiving party to enter into a legally binding written agreement outlining the terms and conditions that will govern the data transfer. This is commonly referred to as a **data use agreement, data transfer and use agreement, data access agreement, and/or a research collaboration agreement.** For purposes of clarity, we shall call them collectively "data use agreements ("DUAs")." DUA's are required under the Privacy Rule and must be entered into ***before*** there is any use or disclosure of data to an outside institution or party. There are varying types of data, which require varying levels of protection.

Data Use Agreements ("DUA") for ALL CWRU schools are overseen by the Office of Research Administration ("ORA"). DUAs may only be signed by an official authorized institutional signatory from ORA, which means that only Joan Schenkel can sign your DUA. DUAs may not be signed by CWRU faculty and/or staff members in the absence of institutional approval.

WHEN DO I NEED A DUA?

A DUA must be entered into ***before*** there is any use or disclosure of data to an outside party. Therefore, you will need a DUA consult any time you intend to share, access, and/or otherwise appropriate data in the furtherance of any study or research project in which you plan to engage.

If the exchange of data, in any form, is part of a research agreement or research collaboration agreement, you need to DISCUSS ADDING DUA TERMS TO THE PRIME AGREEMENT FROM THE BEGINNING.

As part of AWARD SET-UP and NEGOTIATION, it should be determined whether data transfer will be required to complete the AIMS of the Project. If so, DATA USE terms need to be inserted into that Agreement.

WHERE AND HOW DO I OBTAIN A DUA?

In order to determine whether a DUA is required and/or which type of DUA you need for your specific purposes, you will need to work with the Office of Research Administration. Below you will find more details on how to obtain your DUA. The first step is to complete the required **DUA Request Form**.

What is Research Data?

CWRU is concerned with the transfer of human subjects' derived RESEARCH DATA. Research Data is defined as the originally recorded factual material, commonly accepted in the scientific community as necessary to validate research findings.

Research Data includes, but is not limited to, laboratory notebooks, photographs, genetic sequences, test responses, slides, algorithms, models, methodologies, SOP's, database contents, spectra, transcripts as well as the records that are necessary for the reconstruction and evaluation of reported results of research and the events and processes leading to those results, regardless of the form or the media on which they are recorded.

Types of Data

There are many types of data. However, CWRU is only concerned with the transfer and sharing of human subjects' derived research data that is either:

(1) PHI, (2) PII, (3) De-Identified, (4) De-Identified Non-Human Subjects', (5) De-Identified Non-Medical (i.e., financial, Geodata, Environmental, etc.), and (6) Limited Data Sets

Personal Health Information (PHI)

IRB submission REQUIRED!!!

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 Clearinghouses
(2) **Protected information includes**

- Information your Doctors, Nurses, and other health care providers put in your medical record,
- Conversations your Doctor has about your care and/or treatment with nurses and others,
- Information about you 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.

Personal Identifiable Information (PII)

IRB submission REQUIRED!!!

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.

PII is information that:

- Directly identifies an individual
  - Name, address, Social Security number or other identifying number or code, telephone number, email address, etc.
  - By which an agency intends to identify specific individuals in conjunction with other data elements
    - i.e., Indirect Identification

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.

De-Identified Data

IRB submission MAY or MAY NOT be REQUIRED!!!

ORA DUA Team will make a determination as to whether or not submission is required!

De-Identified Data is data that is devoid of any identifiers. This means that the data, when used alone or when combined with other data, cannot be used to identify an individual who is the subject of that information.

The following identifiers of the individual and/or their relatives, employers, or household members MUST be removed for data to be considered De-Identified Data:

(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.

(2) All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and
   a. 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.

(3) 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
   a. *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 the subject of the information*

De-Identified Data Human Subjects' Data can be CODED DATA which will require IRB Review/Determination because there is a way to link the information back to identifiable information. ORA DUA Team will ask that CWRU is NOT provided with access to the code/key to any data it receives.

De-Identified Data Non-Human Subjects' Data is data which is completely de-identified and non-coded. Here there is no interaction with any living individual and there is no identifiable private information being shared. IRB Review/Determination is NOT REQUIRED; however, ORA DUA Team will be responsible for making this determination.

Limited Data Set

IRB submission REQUIRED!!!

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

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) URLs;
(14) IP address numbers;
(15) Biometric identifiers (including finger and voice prints); *and*
(16) Full-face photos (or comparable images)

The health information that may remain in the disclosed information includes:

(1) Dates such as admission, discharge, service, DOB, DOD etc.; *and/or*
(2) City, state, 5-digit zip code; *and/or*
(3) Ages in years, months, days, or hours.

Stand Alone DUA Processes

Data Use Agreements that are NOT a part of a Sponsored Research Agreement, Research Collaboration Agreement, or other Award.

INCOMING DATA PROCESS

aka RECEIVING data or CWRU as Receiver

When obtaining data from an outside third-party, CWRU researchers and staff should follow the steps outlined here and further detailed in the following sections:

(1) Go to **DUA Guidance & Information Sheet** and pre-screen all the questions that will be requested of you on the DUA Request Form. A physical copy of this document is located in the DOCUMENTS section of this manual.

(2) Once you have read over and prepared your responses, please submit your initial data request to ORA by completing the **DUA Request Form**.

- NOTE: You cannot go <BACK> during the intake form. Therefore, if you submit an incomplete form or have made errors, you can either reach out to the ORA DUA Team via CWRU-DUA@case.edu and notify them of the issues OR you can wait and the ORA DUA Team will reach out to you with a retake link, new form request, or request a meeting for further clarification.
- NOTE: As part of your submission – please attach any applicable documents, such as a DUA Form submitted by the data Provider, IRB protocol template, IRB approval or exemption letter, IRB consent forms, Data Security Plan protocol, copy of your NOA, etc.

(3) Once you click "Submit" the DUA Request Form will automatically be sent to the ORA DUA Team for review. We will reach out to you with questions or direction for further processing.

- NOTE: The Provider will either have provided you with an unexecuted draft DUA for review and negotiation by your ORA DUA Team (which should have been uploaded with your Data Request Form) or the ORA DUA Team will reach out to the Provider for an appropriate document.
- NOTE: If more information is required, the ORA DUA Team will reach out and explain the circumstances and advise you how to proceed.
- **NOTE: There are some instances where a DUA may not be required. For instance, if the provider of the data does not require a DUA and the data is not human subjects' research, then CWRU will not require you to obtain a DUA. *This determination can only be made and approved by the ORA DUA Team.***
-

(4) Next Steps… the ORA DUA Team will reach out to you with the appropriate template and will request that you complete specific sections of the form. Specific directions for each standard form used are listed in the TEMPLATE DIRECTIONS SECTION of this manual.

(5) Once you have completed the forms, you will send them back to CWRU-DUA@case.edu. The ORA DUA Team will then negotiate, if needed, with the Provider and reach a mutually acceptable agreement as to the data transfer terms.

(6) Once completed, the DUA must be signed by Joan Schenkel or Meghan Schane-Rambert and by an Authorized Institutional Signatory Official from the Provider organization.

(7) A fully executed copy of the completed DUA will then be sent to you and the Provider.

OUTGOING DATA PROCESS

aka SENDING data or CWRU as PROVIDER

The process for outgoing or sending data is similar to that required for incoming data, in that all DUA's must go through the ORA DUA Team, DUA Process, and are required to be signed by Joan Schenkel (CWRU) and an Authorized Institutional Signatory Official of the Receiving Party.

When sending data to an outside third-party, CWRU Researchers and Staff should follow the steps outlined here and further detailed in the following sections:

(1) Go to **DUA Guidance & information Sheet** and pre-screen all the questions that will be requested of you on the DUA Request Form. A physical copy of this document is located in the DOCUMENTS section of this manual.

(2) Once you have read over and prepared your responses, please submit your initial data request to ORA by completing the **DUA Request Form**.

- NOTE: You cannot go <BACK> during the intake form. Therefore, if you submit an incomplete form or have made errors, you can either reach out to the ORA DUA Team via CWRU-DUA@case.edu and notify them of the issues OR you can wait and the ORA DUA Team will reach out to you with a retake link, new form request, or request a meeting for further clarification.

(3) Once you click "Submit" the DUA Request Form will automatically be sent to the ORA DUA Team for review.

(4) The ORA DUA team will review your submission and contact you with any further questions or clarifications, as needed.

(5) The ORA DUA Team will reach out to you with the appropriate template and will request that you complete specific sections of the form. Specific directions for each standard form used are listed in the TEMPLATE DIRECTIONS SECTION of this manual.

(6) Once you have completed the forms, you will send them back to CWRU-DUA@case.edu. The ORA DUA Team will then negotiate, if needed, with the Receiving party and reach a mutually acceptable agreement as to the data transfer terms.

(7) Once completed, the DUA must be signed by Joan Schenkel or Meghan Schane-Rambert and by an Authorized Institutional Signatory Official from the Receiver organization.

(8) A fully executed copy of the completed DUA will then be sent to you and the Provider

SENDING & RECEIVING DATA (Reciprocal Transfer) …

The process for sending and receiving data is similar to that required for incoming data, in that all DUA's must go through the ORA DUA Team, DUA Process, and are required to be signed by Joan Schenkel (CWRU) and an Authorized Institutional Signatory Official of the Receiving Party.

When sending & receiving data with an outside third-party, CWRU Researchers and Staff should follow the steps outlined here and further detailed in the following sections:

(1) Go to **DUA Guidance & information Sheet** and pre-screen all the questions that will be requested of you on the DUA Request Form. A physical copy of this document is located in the DOCUMENTS section of this manual.

(2) Once you have read over and prepared your responses, please submit your initial data request to ORA by completing the **DUA Request Form**.

NOTE: You cannot go <BACK> during the intake form. Therefore, if you submit an incomplete form or have made errors, you can either reach out to the ORA DUA Team via CWRU-DUA@case.edu and notify them of the issues OR you can wait and the ORA DUA Team will reach out to you with a retake link, new form request, or request a meeting for further clarification.

(3) Once you click "Submit" the DUA Request Form will automatically be sent to the ORA DUA Team for review.

(4) The ORA DUA team will review your submission and contact you with any further questions or clarifications, as needed.

(5) Next Steps… the ORA DUA Team will reach out to you with the appropriate template and will request that you complete specific sections of the form. Specific directions for each standard form used are listed in the TEMPLATE DIRECTIONS SECTION of this manual.

(6) Once you have completed the forms, you will send them back to CWRU-DUA@case.edu . The ORA DUA Team will then negotiate, if needed, with the Receiving party and reach a mutually acceptable agreement as to the data transfer terms.

(7) Once completed, the DUA must be signed by Joan Schenkel or Meghan Schane-Rambert and by an Authorized Institutional Signatory Official from the Reciprocal organization.

(8) A fully executed copy of the completed DUA will then be sent to you and the Provider.

ACCESSING DATA – PORTAL PROCESS

aka viewing data… NO DOWNLOADING shall occur!

The process for accessing data via a Portal applies when you are ACCESSING the data ONLY! This means that you are NOT DOWNLOADING or actually transferring the data outside of the portal. Accessing a Data Portal still requires the data to be requested, reviewed, and approved through the ORA DUA Team Process, and they require signature by Joan Schenkel (CWRU) and (occasionally) by an Authorized Institutional Signatory Official of the Portal.

When accessing the data of a third-party supplier/portal, CWRU Researchers and Staff should follow the steps outlined here and further detailed in the following sections:

(1) Go to the Data Access Portal Website and download their Access Template.

(2) Go to **DUA Guidance & information Sheet** and pre-screen all the questions that will be requested of you on the DUA Request Form. A physical copy of this document is located in the DOCUMENTS section of this manual.

(3) Once you have read over and prepared your responses, please submit your initial data request to ORA by completing the **DUA Request Form**.

NOTE: You cannot go <BACK> during the intake form. Therefore, if you submit an incomplete form or have made errors, you can either reach out to the ORA DUA Team via CWRU-DUA@case.edu and notify them of the issues OR you can wait and the ORA DUA Team will reach out to you with a retake link, new form request, or request a meeting for further clarification.

You should upload a copy of the Data Access Portal's paperwork/request form.

(4) Once you click "Submit" the DUA Request Form will automatically be sent to the ORA DUA Team for review. We will reach out to you with questions or direction for further processing.

(5) The ORA DUA team will review your submission and contact you with any further questions or clarifications, as needed.

(6) Next Steps… the ORA DUA Team will submit your Data Access Request.

(7) A fully executed copy of the completed DUA will then be sent to you for your records.

NOTE: If there is a cost associated with your Data Access request – you will be directed to submit a requisition and in the notes field, you will put that the DUA has already been reviewed and executed by the Director of Data Use Agreements.

PURCHASING DATA PROCESS…

The process for purchasing data requires the data purchase request to be reviewed and approved through the ORA DUA Team Process, and they require signature by Joan Schenkel (CWRU) and (occasionally) by an Authorized Institutional Signatory Official of the Seller.

When purchasing data from a third-party supplier, CWRU Researchers and Staff should follow the steps outlined here and further detailed in the following sections:

(1) Go to the Data Seller's Website and download their Purchasing Agreement.

(2) Go to **DUA Guidance & information Sheet** and pre-screen all the questions that will be requested of you on the DUA Request Form. A physical copy of this document is located in the DOCUMENTS section of this manual.

(3) Once you have read over and prepared your responses, please submit your initial data request to ORA by completing the **DUA Request Form**.

- NOTE: You cannot go <BACK> during the intake form. Therefore, if you submit an incomplete form or have made errors, you can either reach out to the ORA DUA Team via CWRU-DUA@case.edu and notify them of the issues OR you can wait and the ORA DUA Team will reach out to you with a retake link, new form request, or request a meeting for further clarification.

You should upload a copy of the Data Seller's Purchasing Agreement & terms.

(4) Once you click "Submit" the DUA Request Form will automatically be sent to the ORA DUA Team for review.

(5) The ORA DUA team will review your submission and contact you with any further questions or clarifications, as needed.
- The ORA DUA Team will provide you with an unexecuted draft DUA for you to review and sign. You will then submit the completed DUA Draft to CWRU-DUA@case.edu for negotiation with the receiving party by your ORA DUA Team.
- Alternatively, the ORA DUA Team may reach out to you. This most likely means we need more information.

(6) Once completed, the DUA must be signed by Joan Schenkel or Meghan Schane-Rambert.

(7) Next Steps… the ORA DUA Team will submit your Data Purchasing Request to the Seller.

(8) A fully executed copy of the completed DUA will then be sent to you for your records.

(9) You will then submit a requisition and in the notes field, please put that the DUA has already been reviewed and executed by the Director of Data Use Agreements.

dbGaP Data

NCBI Database of Genotypes and Phenotypes Data

dbGaP Database: This database archives the results of studies that have investigated the interaction of genotype and phenotypes and distributes these results to investigators for secondary analysis. The types of data available includes phenotype data, association (GWAS) data, summary level analysis data, SRA (Short Read Archive) data, reference alignment data (BAM), Variant Cell Format data (VCF), expression data, imputed genotype data, image data, etc.

Genotype Data: Data representing the genetic constitution of an individual organism. The genotype of an organism is its complete set of genetic material. Genotype can also be used to refer to the alleles or variants an individual carries in a particular gene or genetic location.

RENEWING dbGaP DATA:

(1) Go to the dbGaP website and note your DUC Addendum #, Project #, and Project Title, as these will be needed by ORA DUA.
(2) Go to **DUA Guidance & information Sheet** and pre-screen all the questions that will be requested of you on the DUA Request Form. A physical copy of this document is located in the DOCUMENTS section of this manual.
(3) Once you have read over and prepared your responses, please submit your initial data request to ORA by completing the **DUA Request Form**.
    a. You will submit to ORA DUA the following:
        i. DUC Addendum #; *and*
        ii. Data Security Plan; *and*
        iii. IRB Approval Letter, IRB Protocol Template, and IRB Consent Forms.
(4) ORA DUA will check DUC Addendum # in dbGaP system to verify if IRB and/or DSP are required (https://www.ncbi.nlm.nih.gov/gap/) ← *use Advanced Search & enter DUC Addendum #*
    a. If IRB or DSP is required:
        i. Verify receipt and/or email PI and request IRB documents
        ii. Review the documents and verify that IRB sharing consent has been given.
        iii. ORA DUA will highlight the consent forms and/or protocol template to show where sharing has been permitted.
        iv. ORA DUA will review the proposed Data Security Plan and verify that it complies with the standard requirements for storing of dbGaP data.
    b. If IRB or DSP is NOT required:
        i. Move to Step (5)
(5) ORA DUA will email the Assoc. VP, Research (Joan Schenkel) with PROJECT #, PI NAME, and PROJECT TITLE along with a note verifying we have reviewed and approved the renewal.
(6) Assoc. VP will go into dbGaP system and electronically sign to renew and send receipt of acknowledgement to cwru-dua@case.edu
    a. You will receive email confirmation of this

CLOSE-OUT dbGaP DATA:

(1) Assoc. VP, Research will email PI with steps to close the dbGaP account
(2) PI will email Assoc. VP, Research (Joan) that it is complete

EMBEDDED DUA's PROCESSES

(Sponsored Research Agreements with DUA Needs and/or Subawards with additional DUA language needed)

Data Use Agreements that are embedded into your Industry Sponsored Research Agreements

Incoming/Outgoing/Reciprocal DUA Process *(for all schools except SOM)*

When a PI is engaged in the initial steps of securing a Sponsored Research Agreement, he/she/they will want to discuss whether the transfer of data is going to occur as part of the Project. CWRU prefers that Data Use terms be embedded into the Agreement. Therefore, to ensure that data use terms are incorporated into a Sponsored Research Agreement, the following steps must be taken:

(1) PI/DA will upload SOW & Budget to Sparta to initiate Agreement generation process.

(2) **Data Transfer Determination.** OSPA Pre-award staff will ask via EMT (Email My Team) in SPARTA if the transfer of human subjects' research data is required as part of the research project.

(3) OSPA Pre-Award staff will EMT CWRU-DUA@case.edu with notice that a DUA review is needed.

(4) ORA DUA Team will review the FP and contact the PI and DA with questions, if needed, to determine whether data language is required to be added to the Agreement.
   a. If one is required, the PI/DA will complete and submit the DUA Request Form (per #5 & #6 below).

(5) PI/DA will go to **DUA Guidance & information Sheet** and pre-screen all the questions that will be requested of you on the DUA Request Form. A physical copy of this document is located in the DOCUMENTS section of this manual.

(6) Once you have read over and prepared your responses, please submit your initial data request to ORA by completing the **DUA Request Form**.
   - NOTE: You cannot go <BACK> during the intake form. Therefore, if you submit an incomplete form or have made errors, you can either reach out to the ORA DUA Team via CWRU-DUA@case.edu and notify them of the issues OR you can wait and the ORA DUA Team will reach out to you with a retake link, new form request, or request a meeting for further clarification.

(7) The ORA DUA team will review your submission and contact you with any further questions or clarifications, as needed.

(8) The ORA DUA Team will then add the appropriate Supplement Terms to the Sponsored Research or Other Agreement.
   a. Supplemental Term Choices will include:
      i. De-Identified Data Incoming Data, Outgoing Data, or Reciprocal Sharing
      ii. De-Identified Data Non-Human Subjects' Incoming Data, Outgoing Data, or Reciprocal Sharing
      iii. PII Data Incoming, Outgoing, or Reciprocal Sharing
      iv. PHI Data Incoming, Outgoing, or Reciprocal Sharing

(9) The ORA DUA Team will then negotiate all terms and conditions of the Sponsored Research Agreement, including the embedded DUA terms.

(10) You will be contacted to verify that you agree and understand the terms of the Agreement, prior to you being asked to sign it (if applicable).

Incoming/Outgoing/Reciprocal DUA Process *(For SOM Only!!)*

When a SOM PI is engaged in the initial steps of securing a Sponsored Research Agreement, he/she/they will want to discuss whether the transfer of data is going to occur as part of the Project. CWRU prefers that Data Use terms be embedded into the Agreement. Therefore, to ensure that data use terms are incorporated into a Sponsored Research Agreement, the following steps must be taken:

(1) SOM PI/DA will upload SOW & Budget to Sparta to initiate Agreement generation process.
(2) **Data Transfer Determination.** SOM Pre-award staff will ask via EMT (Email My Team) in SPARTA if the transfer of human subjects' research data is required as part of the research project.
(3) SOM Pre-Award staff will EMT CWRU-DUA@case.edu with notice that a DUA review is needed.
(4) ORA DUA Team will review the FP and contact the PI and DA with questions, if needed, to determine whether data language is required to be added to the Agreement.
    a. If one is required, the PI/DA will complete and submit the DUA Request Form (per #5 & #6 below).
(5) PI/DA will go to **DUA Guidance & information Sheet** and pre-screen all the questions that will be requested of you on the DUA Request Form. A physical copy of this document is located in the DOCUMENTS section of this manual.

(6) Once you have read over and prepared your responses, please submit your initial data request to ORA by completing the **DUA Request Form**.
    - NOTE: You cannot go <BACK> during the intake form. Therefore, if you submit an incomplete form or have made errors, you can either reach out to the ORA DUA Team via CWRU-DUA@case.edu and notify them of the issues OR you can wait and the ORA DUA Team will reach out to you with a retake link, new form request, or request a meeting for further clarification.

(7) The ORA DUA team will review your submission and contact you with any further questions or clarifications, as needed.

(8) The ORA DUA Team will then add the appropriate Supplement Terms to the Sponsored Research or Other Agreement.
    b. Supplemental Term Choices will include:
        v. De-Identified Data Incoming Data, Outgoing Data, or Reciprocal Sharing
        vi. De-Identified Data Non-Human Subjects' Incoming Data, Outgoing Data, or Reciprocal Sharing
        vii. PII Data Incoming, Outgoing, or Reciprocal Sharing
        viii. PHI Data Incoming, Outgoing, or Reciprocal Sharing

(9) The ORA DUA Team will then insert the appropriate supplemental terms into the Sponsored Research or Other Agreement and upload it to Sparta via the logged comments.
(10) ORA DUA Team will then EMT (Email My Team) the SOM DA and notify them that "ORA DUA Team has reviewed and approved the SRA located in the logged comments below."
(11) SOM OG&C will then negotiate all other terms and conditions of the SRA with the Sponsor and notify the PI and DA upon completion. SOM OG&C will then upload a fully executed agreement to Sparta via the logged comments and EMT CWRU-DUA@case.edu with notice of the FE.

Subaward – FDP Attachment 7

When a PI is engaged in the initial steps of securing a subaward agreement, he/she/they will want to discuss whether the transfer of data is going to occur as part of the AIMS of the Project. CWRU prefers that Data Use terms be embedded into the subaward by use of the FDP Attachment 7 Template. Therefore, to ensure that data use terms are incorporated into a Subaward Agreement, the following steps must be taken:

(1) PI/DA will notify SOM or OSPA of grant award
(2) **Data Transfer Determination.** The SOM or OSPA Pre-award staff will ask via EMT (Email My Team) in SPARTA if the transfer of human subjects' research data is required as part of the subcontract.
(3) SOM or OSPA Pre-Award staff will EMT CWRU-DUA@case.edu with notice that a DUA review is needed.
(4) ORA DUA Team will review the FP and contact the PI and DA with questions, if needed, to determine whether data language is required in the subaward.
    a. If one is required, the PI/DA will complete and submit the DUA Request Form (per #5 & #6 below).

Note: Grant administrators or PIs can start the data transfer approval process if they know data transfer is required for the project subcontract.

(5) PI/DA will go to **DUA Guidance & information Sheet** and pre-screen all the questions that will be requested of you on the DUA Request Form. A physical copy of this document is located in the DOCUMENTS section of this manual.
(6) Once you have read over and prepared your responses, please submit your initial data request to ORA by completing the **DUA Request Form**.
    - NOTE: You cannot go <BACK> during the intake form. Therefore, if you submit an incomplete form or have made errors, you can either reach out to the ORA DUA Team via CWRU-DUA@case.edu and notify them of the issues OR you can wait and the ORA DUA Team will reach out to you with a retake link, new form request, or request a meeting for further clarification.
(7) 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 and will email the PI a blank Attachment 7 for the PI to complete. See TEMPLATE DIRECTIONS SECTION for specific instructions on how to complete the Attachment 7.
(8) PI/DA will return a completed description of data section of Attachment 7 (provided to the PI by the ORA DUA Team) to cwru-dua@case.edu and the DUA staff will confirm the data described matches the DUA Request Form Responses
(9) DUA staff will upload the completed Attachment 7 to Sparta (via a logged comment) for its inclusion in the subaward packet, with an EMT (Email My Team) to the DA and PI that the "ORA DUA Team has reviewed and approved the Attachment 7 provided in the logged comments below."

Data with Special Forms/Procedures

CWRU currently has (or will have) Master Data Use Agreements in place or specific mutually agreed upon arrangements with the following organizations: Cleveland Clinic, MetroHealth Hospital, University Hospital, and the Veteran's Association

The Cleveland Clinic Foundation (CCF)

The Cleveland Clinic and CWRU have a Master Data Use Agreement in place, which requires us to use the CCF Addendum (located in the TEMPLATES sections). To receive data from, send data to, or share data with, CCF, please follow the steps below…

This process is the same, whether you are receiving data and/or accessing data. When obtaining data from an outside third-party, CWRU researchers and staff should follow the steps outlined here and further detailed in the following sections:

(1) Go to **DUA Guidance & information Sheet** and pre-screen all the questions that will be requested of you on the DUA Request Form. A physical copy of this document is located in the DOCUMENTS section of this manual.

(2) Once you have read over and prepared your responses, please submit your initial data request to ORA by completing the **DUA Request Form**.

- NOTE: You cannot go <BACK> during the intake form. Therefore, if you submit an incomplete form or have made errors, you can either reach out to the ORA DUA Team via CWRU-DUA@case.edu and notify them of the issues OR you can wait and the ORA DUA Team will reach out to you with a retake link, new form request, or request a meeting for further clarification.

(3) Once you click "Submit the ORA DUA team will review your submission and contact you with any further questions or clarifications, as needed.

- If APPROVED, the Provider will either provide you with an unexecuted draft DUA for review and negotiation by your ORA DUA Team or the ORA DUA Team will reach out to the Provider for the appropriate document.
- If NOT Initially Approved, the ORA DUA Team will reach out and explain the circumstances and advise you how to proceed. This means we need more information.

(4) The ORA DUA Team will complete the CCF Addendum Template.

(5) Once we have completed the form, it will be sent to CCF for processing and review.

(6) Once completed, the DUA must be signed by Joan Schenkel and by an Authorized Institutional Signatory Official from the Provider organization.

(7) A fully executed copy of the completed DUA will then be sent to you and the Provider.

CCF-CWRU Addendum Example

EXHIBIT A

DATA TRANSFER ADDENDUM

This Data Transfer Addendum ("Addendum"), effective as of the full execution hereof ("Effective Date"), is issued under the Master Data Use Agreement made effective as of February 1, 2020 (the "Master DUA"), by and between Case Western Reserve University ("CWRU") and The Cleveland Clinic Foundation ("CCF") and is regarding certain Data disclosed or to be disclosed for the purpose of the Parties completing certain research activities, as further described below.

This Addendum is governed by the terms and conditions of the Master DUA, which is incorporated herein by reference. Capitalized terms used but not defined herein have the same meanings as set forth in the Master DUA.

The Party providing Data is (i.e., the Discloser):

☐ CWRU ☐ CCF ☐ Both parties

The Data being provided is classified as:

☐ a de-identified data set ☐ a limited data set

Identify the Institutional Review Board study from which the Data is being provided, as applicable:

CWRU:
CCF:

Identify the purpose for which the Data is being provided ("Purpose")

Purpose:

Identify each Parties primary researcher:

CWRU:
CCF:

Please select the applicable publication review procedure:

☐ None ☐ Option 3
☐ Option 1 ☐ Option 4
☐ Option 2 ☐ Option 5
☐ Custom: insert custom language

Any notices or reporting to be given hereunder to a Party shall be made via U.S. Mail or express courier to such Party's address given below:

As to CWRU:
Case Western Reserve University
Office of Research Administration
10900 Euclid Avenue, Nord 6th Floor
Cleveland, OH 44106-7015
Attn: Exec. Dir, Contracts and DUAs

With a copy to:
Case Western Reserve University
Office of Research Administration
10900 Euclid Avenue, Nord 6th Floor
Cleveland, OH 44106
Attn: Director, Contracts

As to CCF:
The Cleveland Clinic Foundation
9500 Euclid Avenue,
Cleveland, OH 44195
Attn:

With copy to:
The Cleveland Clinic Foundation
Law Department – Research Contracts
3050 Science Park Drive (Mail code: AC321)
Beachwood, OH 44122

University Hospitals (UH)

CWRU and University Hospitals share a unique relationship in that CWRU Faculty are also UH Doctors and we have an Affiliation Agreement with UH. Anytime a data transfer requires the use of UH data, the following terms are required:

Additional Terms and Conditions:

1. Nothing herein shall authorize the Recipient to use or further disclose the Data in a manner that would violate the requirements of Provider under 45 CFR 164.514.
2. Recipient shall not use or further disclose the Data other than as permitted by this Agreement or as otherwise required by law.
3. Recipient shall report to the Provider any use or disclosure of the Data not provided for by this Agreement within 3 business days of when it becomes aware of such use or disclosure.
4. Provider is a HIPAA Covered Entity, and the Data will be a Limited Data Set as defined by the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). In accordance with Section 164.514(e)(2) of the HIPAA Privacy Rule, the Data shall exclude the following direct identifiers of the individual or of relatives, employers, or household members of the individual:
    i. Names;
    ii. Postal address information, other than town or city, State, and zip code;
    iii. Telephone numbers;
    iv. Fax numbers;
    v. Electronic mail addresses;
    vi. Social security numbers;
    vii. Medical record numbers;
    viii. Health plan beneficiary numbers;
    ix. Account numbers;
    x. Certificate/license numbers;
    xi. Vehicle identifiers and serial numbers, including license plate numbers;
    xii. Device identifiers and serial numbers;
    xiii. Web Universal Resource Locators (URLs);
    xiv. Internet Protocol (IP) address numbers;
    xv. Biometric identifiers, including finger and voice prints; and
    xvi. Full face photographic images and any comparable images.

If the Data being provided is coded, the Provider will not release, and the Recipient will not request, the key to the code.

5. Recipient will not use the Data, either alone or in concert with any other information, to make any effort to identify or contact individuals who are or may be the sources of Data without specific written approval from Provider and appropriate Institutional Review Board approval, if required pursuant to 45 CFR 46. Should Recipient inadvertently receive identifiable information or otherwise identify a subject, Recipient shall promptly notify Provider and follow Provider's reasonable written instructions, which may include return or destruction of the identifiable information.
6. By signing this Agreement, Recipient provides assurance that relevant institutional policies and applicable federal, state, or local laws and regulations (if any) have been followed, including the completion of any IRB or ethics review or approval that may be required.
7. The parties agree to take such action as is necessary to amend this Agreement, from time to time, in order for the Provider to remain in compliance with the requirements of HIPAA.

The MetroHealth System (METRO)

We are currently working on a Process/Procedure with Metro that will include a standard template…

STAY TUNED…

The Veteran's Association (VA)

We are currently working on a Process/Procedure with the VA, which will include standard templates (which will be located in the TEMPLATES section, upon agreement with the VA) …

GENERAL INFORMATION:

- To do research with the VA, you MUST have a VA appointed Collaborator.
  - Only VA Paid Investigators can be the PI on a research Project.
  - CO-PIs are permissible as long as one (1) is a VA Paid Investigator.
- The VA does not have a specific procedure for INCOMING DATA, as this is rare
- The VA does not have a specific procedure for RECIPROCAL DATA, as this is rare.
- Any data PHYSICALLY leaving the VA, MUST have a DUA

VA OUTGOING DATA PROCESS: *If CWRU PI is NOT also a VA PI*

(1) CWRU PI shall identify a VA PI with whom he/she/they would like to collaborate with

(2) CWRU PI shall submit an IRB determination request to CWRU IRB

(3) CWRU PI shall create a Data Security Plan (DSP)

   a. You must submit the approved plan and/or email from Cal Frye confirming the approved plan

(4) CWRU PI & VA PI will submit the following documents to VA IRB/Privacy Officers:
   a. Protocol,
   b. Informed Consent/HIPAA Authorization,
   c. HIPAA Waiver (if applicable),
   d. Data Management and Access Plan,
   e. VA 10-250 VA Research Privacy Review Checklist,
   f. ISSO Enterprise Research Data Security Plan,
   g. Project Cover Sheet,
   h. All recruitment documentation (if applicable).

(5) CWRU PI shall submit the DUA Request Form through CWRU

   a. **DUA Request Form**

(6) VA IRB/Privacy Office will work with VA PI on agreement to determine data type and the appropriate template for use

   a. VA will submit the appropriate agreed upon template to CWRU for use

(7) CWRU PI will receive an email message from CWRU DUA Team with either a request for more information or a request for the PI to read and acknowledge that he/she/they have read and understand the terms of the data transfer

(8) CWRU DUA Team will then process request and contact VA to review Agreement

   a. VA Contacts: Joe Picklo (joseph.picklo@va.gov) or Tomica Jefferson (tomica.jefferson@va.gov)

(9) VA will review and comment (if necessary) and then the VA will then create a clean copy and send to CWRU-DUA@case.edu

(10) CWRU will review, sign, and return to VA for a FE Agreement

DOCUMENTS

DUA Intake Questions & Guidance
Human Subjects' Classification Tool
Data Security Plan Options & Contact Information

DUA Guidance & Information Sheet

This document provides all the request form questions, when they will appear, and guidance to help you respond to each question. Some questions are conditional, so you may not see all questions as you complete the form.

Guidance will appear in italics and yellow.

If you discover you need to make corrections/revisions to sections of the DUA Request Form, please email cwru-dua@case.edu and request that a link to your survey be resent so you may make edits to the survey or inform them of the errors and provide corrections. Please note: This option is only available after you have submitted the form.

1. Name of the CWRU Investigator Requesting the Data Use Agreement or Data Access Agreement
2. Project Title
3. Department
4. School
5. Investigator's email address
6. Investigator's phone number
7. Name of the person completing the form, if different from the Investigator
8. Email address of the person completing the form, if different from the Investigator
9. Phone number of the person completing the form, if different from the Investigator
10. Is this request for a new data use/data access agreement, or a renewal of an existing data use/data access agreement?
    a. New
    b. Renewal

Renewal Questions: *This section will appear if you indicate that your agreement is the renewal of an already existing agreement.*

1. Upload the renewal agreement. *This is an optional field.*
2. Have any of the conditions of the agreement changed?
    a. Yes: Describe below
    b. No
3. What is the CWRU Investigator's role in the project for which the data transfer or access is requested?
    a. Lead PI of the funded project
    b. PI of a subcontract to CWRU
    c. Key personnel on a funded project, but not the PI.
    d. Collaborator without sponsored funding
4. Indicate the reason this data use agreement or data access agreement is being requested:
    a. To transfer data for a fully executed sponsored project agreement. Include the FP number below. *Providing the FP number will easily allow staff to find the agreement and see the data use terms and conditions. The FP number is the number in SPARTA used to identify the proposal.*
    b. To transfer data for a newly awarded/pending agreement that is in the process of being executed. Indicate the start date and FP number below. *Providing the FP number will easily allow staff to find the agreement and see the data use terms and conditions. The FP number is the number in SPARTA used to identify the proposal.*
    c. To collaborate with another Investigator where there is no funding and/or executed agreement/contract *Choose this option when you intend to send or receive data to an individual at another institution when there is NO funding.*
    d. To access data through a portal at an external institution.
    e. To transfer data from a publicly available source. (Provide link below)
    f. To transfer a controlled access data set (Identify below)
    g. Other- *Choose this option and describe the data transfer reason if it is not stated above.*
5. Name of the organization CWRU is providing data to or receiving data from:

After you respond to the renewal question you will be asked to provide contact information. See the contact information section below.

Data Transfer Information –*This section of the request form has branching logic based upon your responses.*

1. What is the CWRU Investigator's role in the project for which the data transfer or access is being requested?
    a. Lead PI of the funded project
    b. PI of a subcontract to CWRU
    c. Key personnel on a funded project, but not the PI
    d. Collaborator without sponsored funding
2. Indicate the reason this data use agreement or data access agreement is being requested:
    a. To transfer data for a fully executed sponsored project agreement. Include the FP number below. *For DUAs for fully executed agreements, questions regarding funding will appear and are required. They are listed below under Funded Agreement Questions.*
    b. To transfer data for a newly awarded/pending agreement that is in the process of being executed. Indicate the start date and FP number below. *Providing the FP number will easily allow staff to find the agreement and see what type of data use agreement is needed.*
    c. To collaborate with another Investigator where there is no funding and/or executed agreement/contract.
    d. To access data through a portal at an external institution. (Provide link below)
    e. To transfer data from a publicly available source. (Provide link below)
    f. To transfer data from a controlled access data set (Identify below)
    g. Other

3. Briefly describe the data you intend to transfer, receive, or access. *This box will expand. The details of the description you provide will assist staff reviewing your request form in determining the type of data use agreement that is needed.*
4. Is the data to be transferred originally collected as part of a human subjects' research project conducted by a CWRU Investigator or a project collaborator*?

*According to 45 CFR 46, *a human subject is "a living individual about whom an investigator (whether professional or student) conducting research: Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or Obtains, uses, studies, analyzes, or generates identifiable private information, or identifiable biospecimens."*

Respond yes to this question if the data that will be transferred was originally collected under an IRB protocol. As a result of a yes response additional questions will appear. See section below.

Yes
No

5. Was the data obtained from living individuals? *Respond no if the data is limited to data on deceased individuals. (Please note, HIPAA regulations may still apply.*

Yes
No

By responding "Yes" to either question 4 or 5 additional questions about human subject research will appear. They are listed in the General Human Subjects Section Below.

6. Is this data being transferred across international borders?
7. Will the research data generated from use of the transferred data be submitted to or held for inspection by the FDA? (This may be the case for testing an in-vitro diagnostic device or software as a medical device, as the FDA defines human subject differently than described above).
    a. Yes
    b. No

8. For the requested Data Transfer and Use Agreement (DTUA), the CWRU Investigator is
    a. Providing Data
    b. Receiving Data (*If CWRU is receiving data you will be asked to respond to the Incoming Data Questions.)*
    c. Accessing Data

9. Upload a copy of the Data Use Agreement, Data Access Agreement, or Data Licensing Agreement that is associated with this request. If multiple agreements are associated with this request, please assemble them all into a single PDF and upload.

General Human Subjects Questions This question will appear if you answer yes to either human subjects' question.

1. Which of the following applies to the human subjects' data you want to transfer? *Check all that apply*.

- Protected Health Information (From a covered entity) *(If you choose PHI, IRB protocol information will be required. See the IRB section for specific questions)*
- Limited Data Set *(If you choose limited data set. responses regarding the data set will be required. See the Limited Data Set section for the specific questions.)*
- Personal data from someone in the EU or EEA *(If you choose this option IRB protocol information will be required. See the IRB section for specific questions)*
- Student Data
- Personally Identifiable Information *(If you choose PII, IRB protocol information will be required. See the IRB section for specific questions)*
- De-Identified or Fully Anonymized Data: Data have been stripped of all identifying information and there is no way that anyone (provider or recipient) could link it back to the subjects from whom it was originally collected (through a key to a coding system or by any other means)
  (If you choose De-Identified or Fully Anonymized Data, the Human Subjects' Determination Section will appear. See Human Subjects' Determination Section below for the specific questions.)
- Coded Data: Identifying information that allows someone to readily ascertain the identity of an individual has been replaced with a number, letter, symbol (i.e., Code), and a key to decipher the code exists (even if you do not have access to it), allowing the data to be linked back to an individual. *If you choose Coded Data, the Human Subjects' Determination Section will appear. See Human Subjects' Determination Section below for the specific questions.*
- Genetic Data: *If you choose Coded Data, the Human Subjects' Determination Section will appear. See Human Subjects' Determination Section below for the specific questions. Additionally, you will be asked a question regarding the genetic data. See the Genetic Data section below for the question.*
- Other (Describe below)

IRB Protocol Questions

1. The data you are intending to access, receive, or transfer may require oversight for research involving human subjects. Therefore, IRB approval for data transfer or receipt may be required. What is the status of your IRB? Choose the IRB status below or indicate if you believe the project does not require IRB oversight.
    - Approved (Provide IRB approval numbers below) *(If your IRB protocol is approved you will be required to provide additional information in the Approved IRB section)*
    - Submitted to IRB (Provide submission date)
    - Not submitted to IRB (Provide approximate planned submission date)
    - I do not believe the activities with this data are human subjects' research.
2. Which IRB will review/approve or has reviewed/approved your IRB protocol?
    - CWRU IRB
    - UH IRB
    - Other (Name IRB below)
    - NA

Approved IRB

1. Upload a copy of your IRB protocol template.
2. Upload a copy of your IRB approval letter.
3. Does the informed consent form that subjects signed upon entering the study or the relevant IRB protocol, permit data disclosure for the contemplated DUA purpose?
    - Yes
    - No
4. Upload a copy of your consent form.

Limited Data Set Questions

1. Describe the limited data set.
2. Indicate which of the data identifiers are present in the data you want to transfer
    - Names
    - Addresses
    - Telephone Numbers
    - Fax Numbers
    - E-Mail Addresses
    - Social Security Numbers
    - Driver's License Numbers
    - Medical Record Numbers
    - Health Plan Beneficiary Numbers
    - Account Numbers
    - Certificate License Numbers
    - Vehicle Identifiers and serial number including license plates
    - Device Identifiers
    - URLs
    - IP Address Numbers
    - Biometric Identifiers (including finger and voice prints)
    - Full face photographs (or comparable images)
    - Dates such as admission, discharge, DOB, DOD
    - City, State, Five Digit Zip Code
    - Ages in years, months, days, or hours

Genetic Data Question

1. Will whole genome sequence data be generated or received for this project?

Human Subjects' Research Determination -Responses to the questions below will enable ORA staff to assess whether the proposed work using the data you are intending to receive, or access requires IRB oversight.

1. Briefly describe the de-identified, coded data set or genetic data
2. Is the information:
   - ○ Unidentifiable data obtained from a commercial provider; or
   - ○ Unidentifiable data obtained from a provider that is prohibited from releasing identifiers due to established regulations or policies
     a. No
     b. Yes
     c. N/A if CWRU is providing data to another institution
3. Was the data collected specifically for the proposed research through an interaction or intervention with living individuals by CWRU investigators or other collaborators? *This interaction or intervention could have been done by CWRU researchers or by an individual outside CWRU who is engaged in the research as a collaborator for this specific project.*
   a. Yes (Answer yes if your analysis is part of the original aims of the study for which the data were collected.)
   b. No (Answer no if your work is secondary analysis that is different from the original study.)
4. Can the *recipient* link the data **directly** to identifiable private information of living individuals?
   a. Yes
   b. No
5. Can the *provider* link the data **directly** to identifiable private information of living individuals?
   a. Yes
   b. No
6. Does the data *provider* meet the definition of an "Investigator" in the recipient's research? *An Investigator is a person responsible for the planning, execution, and reporting for the research project requiring the transfer of data.*
   Yes, the provider is engaged as an investigator on the research project that is requiring the data transfer. No, the provider is solely providing the data.
7. Is the data provided with a code linking it to identifiable private information of living individuals?
   a. Yes
   b. No
8. Can the *recipient* readily ascertain the identities of the individuals to whom the data pertain?
   Examples of situations in which the recipient **cannot** link the data to living individuals include:
   - the key to decipher the code is destroyed before the research begins; or
   - the investigators and the holder of the key to the code enter into an agreement preventing the release of the key to investigators under any circumstances; or
   - there are IRB-approved written policies in place preventing the release of the key under any circumstances; or
   - there are other legal requirements prohibiting the release of the key under any circumstances.
     a. Yes
     b. No

Incoming Data Questions

1. Where do you intend to store and/or analyze the data? Check all that apply.
   -Secured Research Environment
   -CWRU REDCap Not SRE
   -CWRU Qualtrics
   -CWRU Google Drive
   -CWRU High Performance Computing Cluster
   -Departmental Server
   -Google Cloud Platform
   -CWRU Desktop
   -UH REDCap
   -Other: Describe below
   -CWRU BOX
   -CWRU Microsoft Sharepoint
   -CWRU Research Virtual Machine
   -Amazon Web Services
   -CWRU Laptop
2. Provide the name/phone number and email for the person responsible for data security?
3. Is the data from CMS (Medicaid, ResDAC, Medicare), dbGap, or another restricted data set?
   - Yes *(You will be required to answer additional data security questions in the Data Security section. See Data Security section for the specific questions.)*
   - No

Data Security Questions

1. What organization is providing the dataset?
   - dpGap
   - CMS (Medicaid, ResDAC, Medicare)
   - Other, describe below
2. What is the project number for the data request?
3. What specific datasets are you requesting to transfer? (In the case of CMS Data, these answers must match the data sets listed in the approval letter)
4. Where do you intend to analyze the dataset(s)? Check ALL that apply.
   - Virtual or physical servers within the [U]Tech Secure Research Environment
   - Virtual or physical servers within an [U]Tech data center (e.g., Kelvin Smith Library)
   - Using the [U]Tech High Performance Computing Cluster
   - CWRU-owned desktop
   - CWRU-owned laptop
5. List all the individuals (first name, last name, CWRU net ID) who will have access to the data.
6. How will you protect access to the data? Check all that apply.
   - CWRU net ID login required
   - Air-gapped workstation
   - Locked doors for room(s) with laptop, workstation, or desktop computer
   - Keycard/Swipe Card/Scan Card Access to Workstation Room for Data Analysis
   - Analysis Machines secured to workspace (e.g., chain locks on desktop computers)
   - Other
7. Upload a copy of the approval letter from the entity providing the data.
8. Upload an email from UTech indicating they approve of your data storage and security plan.
   - We can begin the review of your DUA without an approval from Utech, however your DUA will not be executed without approval of your data security plan

Funded Agreement Questions are required for fully funded agreements.

1. Attach the Notice of Grant Award or Grant/Contract Agreement from the sponsor.

Contact Information

1. Contact Name of Person
2. Contact Title
3. Contact Phone
4. Contact Email
5. Role of Contact
   - Investigator -*Person at the other institution with whom you will be sharing data with.*
   - Administrator
   - Other

Directions are included at the end of the request form that allow you to submit the form and receive a copy of your responses.

Please select the right arrow at the bottom of this page to submit your DUA request form and to receive a copy of your responses.

End of DUA Intake Questions/Guidance

Human Subjects' Classification Tool

This is classification tool designed by the Federal Demonstration Partnership to streamline the review of the type of human subject data – this is guidance tool only! Only the CWRU DUA Department, along with the IRB, may make this determination.

FDP Tool for Classifying Human Subjects Data

<table>
<tr>
<th>18 HIPAA Identifiers that comprise Personally Identifiable Information (PII)</th>
<th>HIPAA – Limited Data Set</th>
<th>FERPA – Personally Identifiable Information</th>
</tr>
<tr>
<td>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).
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
A data set containing any of these identifiers, or parts of the identifier, is considered “identified”</td>
<td>A Limited Data Set must omit all of the HIPAA Identifiers in the left-hand column except for the following:
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 To re-iterate. initials

are always considered PHI/PII

HIPAA – De-identified Data

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:

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</td>
<td>In the context of FERPA, PII includes, but is not limited to:
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:
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:
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</td>
</tr>
</table>

Data Security Plan Options

Research Computing Facilitator & Compliance Technologist:
Cal Frye: cxf244@case.edu

Secure Options Include:

**SRE (*please note – this option has a fee) **
UH REDCap*
CWRU REDCap Not SRE*
Other: Describe below
CWRU Qualtrics
CWRU BOX
CWRU Google Drive
CWRU Microsoft Sharepoint
CWRU High Performance Computing Cluster*
CWRU Research Virtual Machine
Departmental Server
Amazon Web Services
Google Cloud Platform
CWRU Laptop
CWRU Desktop

These options are not available for ALL types of data as different data requires different levels of security. This is just s list of options for your convenience.

CWRU ORA DUA preferred data security storage options

Templates & Directions

The Federal Demonstration Partnership is a program convened by the Government-University-Industry Research Roundtable of the National Academies. Its purpose is to reduce the administrative burdens associated with research grants and contracts.

CWRU uses these templates for University-to-University data transfers as well as other governmental agencies.

When data exchange is required as part of a subcontract or subaward that involved a University or a governmental agency, we prefer to use the FDP Attachment 7 Form, which is included in the subcontract/subaward packet.

CWRU ORA DUA Team completes
PI completes Agreement ID:

FDP Data Transfer and Use Agreement ("Agreement")

Provider:	Recipient:
Provider Scientist Name: Email:	Recipient Scientist Name: Email:
Agreement Term Start Date: Date of last signature below End Date: Three (3) Years after the Start Date	Project Title: Attachment 2 Type: Select Data Type

Terms and Conditions

1) Provider shall provide the data set described in Attachment 1 (the "Data") to Recipient for the research purpose set forth in Attachment 1 (the "Project"). Provider shall retain ownership of any rights it may have in the Data, and Recipient does not obtain any rights in the Data other than as set forth herein.
2) If applicable, reimbursement of any costs associated with the preparation, compilation, and transfer of the Data to the Recipient will be addressed in Attachment 1.
3) Recipient shall not use the Data except as authorized under this Agreement. The Data will be used solely to conduct the Project and solely by Recipient Scientist and Recipient's faculty, employees, fellows, students, and agents ("Recipient Personnel") and Collaborator Personnel (as defined in Attachment 3) that have a need to use, or provide a service in respect of, the Data in connection with the Project and whose obligations of use are consistent with the terms of this Agreement (collectively, "Authorized Persons").
4) Except as authorized under this Agreement or otherwise required by law, Recipient agrees to retain control over the Data and shall not disclose, release, sell, rent, lease, loan, or otherwise grant access to the Data to any third party, except Authorized Persons, without the prior written consent of Provider. Recipient agrees to establish appropriate administrative, technical, and physical safeguards to prevent unauthorized use of or access to the Data and comply with any other special requirements relating to safeguarding of the Data as may be set forth in Attachment 2.
5) Recipient agrees to use the Data in compliance with all applicable laws, rules, and regulations, as well as all professional standards applicable to such research.
6) Recipient is encouraged to make publicly available the results of the Project. Before Recipient submits a paper or abstract for publication or otherwise intends to publicly disclose information about the results of the Project, the Provider will have thirty (30) days from receipt to review proposed manuscripts and ten (10) days from receipt to review proposed abstracts to ensure that the Data is appropriately protected. Provider may request in writing that the proposed publication or other disclosure be delayed for up to thirty (30) additional days as necessary to protect proprietary information.

Please note: Attachment 2 will vary based on the data type selected for this particular transfer

Agreement ID:

7) Recipient agrees to recognize the contribution of the Provider as the source of the Data in all written, visual, or oral public disclosures concerning Recipient's research using the Data, as appropriate in accordance with scholarly standards and any specific format that has been indicated in Attachment 1.

8) Unless terminated earlier in accordance with this section or extended via a modification in accordance with Section 13, this Agreement shall expire as of the End Date set forth above. Either party may terminate this Agreement with thirty (30) days written notice to the other party's Authorized Official as set forth below. Upon expiration or early termination of this Agreement, Recipient shall follow the disposition instructions provided in Attachment 1, provided, however, that Recipient may retain one (1) copy of the Data to the extent necessary to comply with the records retention requirements under any law, and for the purposes of research integrity and verification.

9) Except as provided below or prohibited by law, any Data delivered pursuant to this Agreement is understood to be provided "AS IS." PROVIDER MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE DATA WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS. Notwithstanding, Provider, to the best of its knowledge and belief, has the right and authority to provide the Data to Recipient for use in the Project.

10) Except to the extent prohibited by law, the Recipient assumes all liability for damages which may arise from its use, storage, disclosure, or disposal of the Data. The Provider will not be liable to the Recipient for any loss, claim, or demand made by the Recipient, or made against the Recipient by any other party, due to or arising from the use of the Data by the Recipient, except to the extent permitted by law when caused by the gross negligence or willful misconduct of the Provider. No indemnification for any loss, claim, damage, or liability is intended or provided by either party under this Agreement.

11) Neither party shall use the other party's name, trademarks, or other logos in any publicity, advertising, or news release without the prior written approval of an authorized representative of that party. The parties agree that each party may disclose factual information regarding the existence and purpose of the relationship that is the subject of this Agreement for other purposes without written permission from the other party provided that any such statement shall accurately and appropriately describe the relationship of the parties and shall not in any manner imply endorsement by the other party whose name is being used.

12) Unless otherwise specified, this Agreement and the below listed Attachments embody the entire understanding between Provider and Recipient regarding the transfer of the Data to Recipient for the Project:

   I. Attachment 1: Project Specific Information
   II. Attachment 2: Data-specific Terms and Conditions
   III. Attachment 3: Identification of Permitted Collaborators (if any)

13) No modification or waiver of this Agreement shall be valid unless in writing and executed by duly-authorized representatives of both parties.

Agreement ID:

14) The undersigned Authorized Officials of Provider and Recipient expressly represent and affirm that the contents of any statements made herein are truthful and accurate and that they are duly authorized to sign this Agreement on behalf of their institution.

By an Authorized Official of Provider:	By an Authorized Official of Recipient:
_____ Date	_____ Date
Name: Joan Schenkel	Name:
Title: Associate VP for Research	Title:
Contact Information for Formal Notices:	Contact Information for Formal Notices:
Name: Meghan Schane-Rambert	Name:
Address: 10900 Euclid Ave Sears Library 641 Cleveland, OH 44106	Address:
Email: CWRU-DUA@case.edu	Email:
Phone: (216) 368-5092	Phone:

↑ receiving party will complete

Agreement ID:

Attachment 1
Data Transfer and Use Agreement
Project Specific Information

1. Description of Data:

Instructions to the drafter; delete after completion of this section:

This section of this attachment should provide sufficient information such that each party understands the information that will be transmitted under this Agreement. Examples of information that should be provided include:

* Whether the data is obtained from human subjects and, if so, a description of the population included in the data.
* If the data is from animal subjects, the species of animal the data was obtained using.
* If not from human or animal subjects, a description of the focus of the data.
* The number of subjects and/or experiments included
* Name of the study that the data was obtained under

If there is a particular study that needs to be acknowledged/cited as the source of the data, this information should be included here.

2. Description of Project:

Instructions to the drafter; delete after completion of this section:

This section of this attachment should provide sufficient information such that each party understands the project that the Recipient will perform using the Data. Content of this section will be very similar to the Statement of Work used in other types of Agreements. Examples of information that should be provided include:

* Objective or purpose of the Recipient's work
* A general description of the actions to be performed by the Recipient using the Data and possibly the anticipated results
* Include whether or not the Recipient is permitted to link the Data with other data sets (If yes, be sure to include any special disposition requirements related to the linked data sets in Section 5 of this attachment).

3. Provider Support and Data Transmission:

Provider shall transmit the Data to Recipient: (select one) ☐ electronically or ☐ by mail to:

Name:	
Address:	
Email:	
Phone:	

Agreement ID:

Upon execution of this Agreement, Provider shall send any specific instructions necessary to complete the transfer of the Data to the contact person listed above, if not already included below in this section of Attachment 1.

Instructions to the drafter; delete after completion of this section.

This section of this attachment should also provide sufficient information such that each party understands the level of support the Provider will supply to the Recipient. Examples of information that may be appropriate to include in this section are:

* Format of Data
* Provision of Data dictionary
* Availability of Provider to assist Recipient in understanding the Data structure (e.g. variables, code lists, etc.)
* If/how Data will be revised and resent if errors are found by the Recipient
* Specific instructions necessary to complete the transfer of the Data, if available/appropriate, and any support supplied by the Provider for the transfer.

4. Reimbursement of Costs:

☐ None

☐ As governed by a separate written agreement between the parties
Reimbursement Agreement Reference # (if required):
_____

☐ As set forth herein:

5. Disposition Requirements upon the termination or expiration of the Agreement:

Instructions to the drafter; delete after completion of this section:

This section of this attachment should provide sufficient information such that each party understands the Recipient's obligations with regards to the Data upon the expiration or early termination of this Agreement. If the Recipient is permitted to link the Data with other data sets, be sure to include any special disposition requirements related to the linked data sets in this attachment.

Please note: ATTACHMENT 2 will be selected and sent to you by the ORA DUA team, this Attachment will vary based on data type and will not require any action on the PI/Das part as it is a read-alone page.

Agreement ID:

Attachment 3
Data Transfer and Use Agreement
Identification of Permitted Collaborators (if any)

For all purposes of this Agreement, the definition of "Collaborator Personnel" checked below will pertain:

☐ "Collaborator Personnel" means: None. No collaborators are permitted on the Project.

-OR-

☐ "Collaborator Personnel" means as set forth below and agreed upon between the Parties:

Sample definition language for the drafter; delete if the first option is checked or after a final definition has been agreed between the Parties:

"Collaborator Personnel" means: faculty, employees, fellows, or students of an academic institution, which institution (i) has agreed to collaborate in the Project, (ii) has faculty, employees, fellows, or students who have a need to use or provide a service in respect of the Data in connection with its collaboration in the Project, and (iii) has been made aware of the terms of this Agreement and agreed to comply, and to cause its personnel to comply, with such terms.

An alternative option for (iii); "has executed an agreement that is substantially similar to this Agreement"

CWRU ORA DUA Team completes

PI completes

Agreement ID:

FDP Data Transfer and Use Agreement ("Agreement")

Provider:	Recipient:
Provider Scientist Name: Email:	Recipient Scientist Name: Email:
Agreement Term Start Date: Date of last signature below End Date: Three (3) Years after the Start Date	Project Title: Attachment 2 Type: Select Data Type

Terms and Conditions

1) Provider shall provide the data set described in Attachment 1 (the "Data") to Recipient for the research purpose set forth in Attachment 1 (the "Project"). Provider shall retain ownership of any rights it may have in the Data, and Recipient does not obtain any rights in the Data other than as set forth herein.
2) If applicable, reimbursement of any costs associated with the preparation, compilation, and transfer of the Data to the Recipient will be addressed in Attachment 1.
3) Recipient shall not use the Data except as authorized under this Agreement. The Data will be used solely to conduct the Project and solely by Recipient Scientist and Recipient's faculty, employees, fellows, students, and agents ("Recipient Personnel") and Collaborator Personnel (as defined in Attachment 3) that have a need to use, or provide a service in respect of, the Data in connection with the Project and whose obligations of use are consistent with the terms of this Agreement (collectively, "Authorized Persons").
4) Except as authorized under this Agreement or otherwise required by law, Recipient agrees to retain control over the Data and shall not disclose, release, sell, rent, lease, loan, or otherwise grant access to the Data to any third party, except Authorized Persons, without the prior written consent of Provider. Recipient agrees to establish appropriate administrative, technical, and physical safeguards to prevent unauthorized use of or access to the Data and comply with any other special requirements relating to safeguarding of the Data as may be set forth in Attachment 2.
5) Recipient agrees to use the Data in compliance with all applicable laws, rules, and regulations, as well as all professional standards applicable to such research.
6) Recipient is encouraged to make publicly available the results of the Project. Before Recipient submits a paper or abstract for publication or otherwise intends to publicly disclose information about the results of the Project, the Provider will have thirty (30) days from receipt to review proposed manuscripts and ten (10) days from receipt to review proposed abstracts to ensure that the Data is appropriately protected. Provider may request in writing that the proposed publication or other disclosure be delayed for up to thirty (30) additional days as necessary to protect proprietary information.

Please note: Attachment 2 will vary based on the data type

Agreement ID:

7) Recipient agrees to recognize the contribution of the Provider as the source of the Data in all written, visual, or oral public disclosures concerning Recipient's research using the Data, as appropriate in accordance with scholarly standards and any specific format that has been indicated in Attachment 1.

8) Unless terminated earlier in accordance with this section or extended via a modification in accordance with Section 13, this Agreement shall expire as of the End Date set forth above. Either party may terminate this Agreement with thirty (30) days written notice to the other party's Authorized Official as set forth below. Upon expiration or early termination of this Agreement, Recipient shall follow the disposition instructions provided in Attachment 1, provided, however, that Recipient may retain one (1) copy of the Data to the extent necessary to comply with the records retention requirements under any law, and for the purposes of research integrity and verification.

9) Except as provided below or prohibited by law, any Data delivered pursuant to this Agreement is understood to be provided "AS IS." PROVIDER MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE DATA WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS. Notwithstanding, Provider, to the best of its knowledge and belief, has the right and authority to provide the Data to Recipient for use in the Project.

10) Except to the extent prohibited by law, the Recipient assumes all liability for damages which may arise from its use, storage, disclosure, or disposal of the Data. The Provider will not be liable to the Recipient for any loss, claim, or demand made by the Recipient, or made against the Recipient by any other party, due to or arising from the use of the Data by the Recipient, except to the extent permitted by law when caused by the gross negligence or willful misconduct of the Provider. No indemnification for any loss, claim, damage, or liability is intended or provided by either party under this Agreement.

11) Neither party shall use the other party's name, trademarks, or other logos in any publicity, advertising, or news release without the prior written approval of an authorized representative of that party. The parties agree that each party may disclose factual information regarding the existence and purpose of the relationship that is the subject of this Agreement for other purposes without written permission from the other party provided that any such statement shall accurately and appropriately describe the relationship of the parties and shall not in any manner imply endorsement by the other party whose name is being used.

12) Unless otherwise specified, this Agreement and the below listed Attachments embody the entire understanding between Provider and Recipient regarding the transfer of the Data to Recipient for the Project:

   I. Attachment 1: Project Specific Information
   II. Attachment 2: Data-specific Terms and Conditions
   III. Attachment 3: Identification of Permitted Collaborators (if any)

13) No modification or waiver of this Agreement shall be valid unless in writing and executed by duly-authorized representatives of both parties.

Agreement ID:

14) The undersigned Authorized Officials of Provider and Recipient expressly represent and affirm that the contents of any statements made herein are truthful and accurate and that they are duly authorized to sign this Agreement on behalf of their institution.

By an Authorized Official of Provider:	By an Authorized Official of Recipient:
_____ _____ Date	_____ _____ Date
Name:	Name: Joan Schenkel
Title:	Title: Associate Vice President for Research
Contact Information for Formal Notices:	Contact Information for Formal Notices:
Name:	Name: Meghan Schane-Rambert
Address:	Address: Dir. of Contracts & Data Use Agreements 10900 Euclid Ave, Sears Library 641 Cleveland, OH 44106
Email:	Email: CWRU-DUA@case.edu
Phone:	Phone: (216) 368-5092

Agreement ID:

Attachment 1
Data Transfer and Use Agreement
Project Specific Information

1. Description of Data:

Instructions to the drafter; delete after completion of this section:

This section of this attachment should provide sufficient information such that each party understands the information that will be transmitted under this Agreement. Examples of information that should be provided include:
* Whether the data is obtained from human subjects and, if so, a description of the population included in the data.
* If the data is from animal subjects, the species of animal the data was obtained using.
* If not from human or animal subjects, a description of the focus of the data.
* The number of subjects and/or experiments included
* Name of the study that the data was obtained under

If there is a particular study that needs to be acknowledged/cited as the source of the data, this information should be included here.

2. Description of Project:

Instructions to the drafter; delete after completion of this section:

This section of this attachment should provide sufficient information such that each party understands the project that the Recipient will perform using the Data. Content of this section will be very similar to the Statement of Work used in other types of Agreements. Examples of information that should be provided include:
* Objective or purpose of the Recipient's work
* A general description of the actions to be performed by the Recipient using the Data and possibly the anticipated results
* Include whether or not the Recipient is permitted to link the Data with other data sets (If yes, be sure to include any special disposition requirements related to the linked data sets in Section 5 of this attachment).

3. Provider Support and Data Transmission:

Provider shall transmit the Data to Recipient: (select one) ☐ electronically or ☐ by mail to:

Name:	
Address:	
Email:	
Phone:	

Agreement ID:

Upon execution of this Agreement, Provider shall send any specific instructions necessary to complete the transfer of the Data to the contact person listed above, if not already included below in this section of Attachment 1.

Instructions to the drafter; delete after completion of this section.

This section of this attachment should also provide sufficient information such that each party understands the level of support the Provider will supply to the Recipient. Examples of information that may be appropriate to include in this section are:

* Format of Data
* Provision of Data dictionary
* Availability of Provider to assist Recipient in understanding the Data structure (e.g. variables, code lists, etc.)
* If/how Data will be revised and resent if errors are found by the Recipient
* Specific instructions necessary to complete the transfer of the Data, if available/appropriate, and any support supplied by the Provider for the transfer.

4. Reimbursement of Costs:

☐ None

☐ As governed by a separate written agreement between the parties
Reimbursement Agreement Reference # (if required):
_____

☐ As set forth herein:

5. Disposition Requirements upon the termination or expiration of the Agreement:

Instructions to the drafter; delete after completion of this section:

This section of this attachment should provide sufficient information such that each party understands the Recipient's obligations with regards to the Data upon the expiration or early termination of this Agreement. If the Recipient is permitted to link the Data with other data sets, be sure to include any special disposition requirements related to the linked data sets in this attachment.

Please note: ATTACHMENT 2 will be selected and sent to you by the ORA DUA team, this Attachment will vary based on data type and will not require any action on the PI/Das part as it is a read-alone page.

Agreement ID:

Attachment 3
Data Transfer and Use Agreement
Identification of Permitted Collaborators (if any)

For all purposes of this Agreement, the definition of "Collaborator Personnel" checked below will pertain:

☐ "Collaborator Personnel" means: None. No collaborators are permitted on the Project.

-OR-

☐ "Collaborator Personnel" means as set forth below and agreed upon between the Parties:

Sample definition language for the drafter; delete if the first option is checked or after a final definition has been agreed between the Parties:

"Collaborator Personnel" means: faculty, employees, fellows, or students of an academic institution, which institution (i) has agreed to collaborate in the Project, (ii) has faculty, employees, fellows, or students who have a need to use or provide a service in respect of the Data in connection with its collaboration in the Project, and (iii) has been made aware of the terms of this Agreement and agreed to comply, and to cause its personnel to comply, with such terms.

An alternative option for (iii); "has executed an agreement that is substantially similar to this Agreement"

SENDING & RECEIVING DATA

CWRU ORA DUA Team completes **PI completes**

FDP Reciprocal Data Transfer and Use Agreement ("Agreement")	
Party 1:	Party 2:
Party 1 Scientist Name: Email:	Party 2 Scientist Name: Email:
Party 1 Data Type: Select Data Type	Party 2 Data Type: Select Data Type
Agreement Term Start Date: Date of last execution below End Date: Insert specific end date	Project Title:

Terms and Conditions

1) The Parties shall provide the data set(s) described on Attachment 1 (the "Data") to each other for the research purpose set forth in Attachment 1 (the "Project"). Each Party is a Providing Party when providing Data and a Receiving Party when receiving Data. Providing Party shall retain ownership of any rights it may have in the Data, and Receiving Party does not obtain any rights in the Data other than as set forth herein.

2) Receiving Party shall not use the Data except as authorized under this Agreement. The Data will be used solely to conduct the Project and solely by Receiving Party's Scientist and Receiving Party's faculty, employees, fellows, students, and agents ("Receiving Party Personnel") and Third Party Personnel (as defined in Attachment 3) that have a need to use, or provide a service in respect of, the Data in connection with the Project and whose obligations of use are consistent with the terms of this Agreement (collectively, "Authorized Persons").

3) Except as authorized under this Agreement or otherwise required by law, Receiving Party agrees to retain control over the Data and shall not disclose, release, sell, rent, lease, loan, or otherwise grant access to the Data to any third party, except Authorized Persons, without the prior written consent of Providing Party. Receiving Party agrees to establish appropriate administrative, technical, and physical safeguards to prevent unauthorized use of or access to the Data and comply with any other special requirements relating to safeguarding of the Data as may be set forth in the applicable Attachment 2.

4) Receiving Party agrees to use the Data in compliance with all applicable laws, rules, and regulations, as well as all professional standards applicable to such research.

5) The Parties are encouraged to make publicly available the results of the Project. Before either Party submits a paper or abstract for publication or otherwise intends to publicly disclose information about the results of the Project, the other Party will have thirty (30) days from receipt to review proposed manuscripts and ten (10) days from receipt to review proposed abstracts to ensure that the Data is appropriately protected. The non-publishing Party may request in writing that the proposed publication or other disclosure be delayed for up to thirty (30) additional days as necessary to protect proprietary information. The Parties will together make decisions on jointly authored publications. Authorship will be in accordance with academic and/or scholarly standards.

6) Receiving Party agrees to recognize the contribution of the Providing Party as the source of the Data in all written, visual, or oral public disclosures concerning Receiving Party's research using the Data, as appropriate in accordance with scholarly standards and any specific format that has been indicated in Attachment 1.

7) Unless terminated earlier in accordance with this section or extended via a modification in accordance with Section 12, this Agreement shall expire as of the End Date set forth above. Either Party may terminate this Agreement with thirty (30) days written notice to the other Party's Authorized Official as set forth below. Upon expiration or early termination of this Agreement, Receiving Party shall follow the disposition instructions provided in Attachment 1, provided, however, that Receiving Party may retain one (1) copy of the Data to the extent necessary to comply with the records retention requirements under any law, and for the purposes of research integrity and verification.

8) EXCEPT AS PROVIDED BELOW OR PROHIBITED BY LAW, ANY DATA DELIVERED PURSUANT TO THIS AGREEMENT IS UNDERSTOOD TO BE PROVIDED "AS IS." PROVIDING PARTY MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE DATA WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS. Notwithstanding, Providing Party, to the best of its knowledge and belief, has the right and authority to provide the Data to Receiving Party for use in the Project.

Please note: Attachment 2 will vary based on the data type

9) Each Receiving Party shall be liable for damages, losses, claims, and demands which may arise from its use, storage, disclosure, or disposal of the Data except to the extent (a) prohibited by law and/or (b) caused by the negligence, willful misconduct, or violation of applicable privacy or security laws and regulations by the Providing Party. No indemnification for any damage, loss, claim, demand, or liability is intended or provided by either Party under this Agreement.

10) Neither Party shall use the other Party's name, trademarks, or other logos in any publicity, advertising, or news release without the prior written approval of an authorized representative of that Party. The Parties agree that each Party may disclose factual information regarding the existence and purpose of the relationship that is the subject of this Agreement for other purposes without written permission from the other Party provided that any such statement shall accurately and appropriately describe the relationship of the Parties and shall not in any manner imply endorsement by the other Party whose name is being used.

11) Unless otherwise specified, this Agreement and the below listed Attachments embody the entire understanding between the Parties regarding the transfer of the Data for the Project:

I. Attachment 1: Project-specific Information
II. Party 1 Attachment 2: Data-specific Terms and Conditions
III. Party 2 Attachment 2: Data-specific Terms and Conditions
IV. Attachment 3: Identification of Permitted Third Parties (if any)

In the event of any conflict between the obligations set forth in the applicable Attachment 2 and this Agreement, the obligations set forth in Attachment 2 shall prevail.

12) No modification or waiver of this Agreement shall be valid unless in writing and executed by duly authorized representatives of both Parties.

13) The undersigned Authorized Officials of the Parties expressly represent and affirm that the contents of any statements made herein are truthful and accurate and that they are duly authorized to sign this Agreement on behalf of their institution.

By an Authorized Official of Party 1:	By an Authorized Official of Party 2:
_____ _____	_____ _____
Name: Joan Schenkel Date	Name: Date
Title: Associate Vice President for Research	Title:
Contact Information for Formal Notices:	Contact Information for Formal Notices:
Name: Meghan Schane-Rambert	Name:
Address: 10900 Euclid Ave, Sears Library 641	Address:
Cleveland, OH 44106	
Email: CWRU-DUA@case.edu	Email:
Phone: (216) 368-5092	Phone:

Attachment 1
Reciprocal Data Transfer and Use Agreement
Project-specific Information

1. Description of Project:

Instructions to the drafter; delete after completion of this section:
This section of this attachment should provide sufficient information such that each Party understands the project that the Parties will perform using the Data. Content of this section will be very similar to the Statement of Work used in other types of Agreements. Examples of information that should be provided include:
- Objective or purpose of the Parties' work
- A general description of the actions to be performed by each Party using the Data and possibly the anticipated results
- Whether or not the Parties are permitted to link the Data with other data sets (If yes, be sure to include any special disposition requirements related to the linked data sets in Sections 6 and 7 of this attachment).

2. Description of Party 1 Data:

Instructions to the drafter; delete after completion of this section:
This section of this attachment should provide sufficient information such that each Party understands the information that will be transmitted by Party 1 under this Agreement. If Party 1 will not be sharing any Data under this Agreement, simply indicate "None" in this section and select "None" from the Party 1 Data Type drop-down menu on the face page. Examples of information that should be provided include:
- If the Party 1 Data is obtained from human subjects, a description of the population included in the Party 1 Data
- If the Party 1 Data is from animal subjects, the species of animal the Party 1 Data was obtained using
- If not from human or animal subjects, a description of the focus of the Party 1 Data
- The number of subjects and/or experiments included
- Name of the study that the Party 1 Data was obtained under

If there is a particular study that needs to be acknowledged/cited as the source of the Party 1 Data, this information should be included here.

3. Party 1 Disposition Requirements upon the termination or expiration of the Agreement

Instructions to the drafter; delete after completion of this section:
This section of this attachment should provide sufficient information such that each Party understands the Receiving Party's obligations with regards to the Party 1 Data upon the expiration or early termination of this Agreement. If the Receiving Party is permitted to link the Data with other data sets, be sure to include any special disposition requirements related to the linked data sets in this attachment.

4. For Party 1, send Data Select One to:
   Name:
   Email:
   Address:

   Phone:

5. Description of Party 2 Data:

Instructions to the drafter; delete after completion of this section:
This section of this attachment should provide sufficient information such that each Party understands the information that will be transmitted by Party 2 under this Agreement. If Party 2 will not be sharing any Data under this Agreement, simply indicate "None" in this section and select "None" from the Party 2 Data Type drop-down menu on the face page. Examples of information that should be provided include:

- If the Party 2 Data is obtained from human subjects, a description of the population included in the Party 2 Data
- If the Party 2 Data is from animal subjects, the species of animal the Party 2 Data was obtained using
- If not from human or animal subjects, a description of the focus of the Party 2 Data
- The number of subjects and/or experiments included
- Name of the study that the Party 2 Data was obtained under

If there is a particular study that needs to be acknowledged/cited as the source of the Party 2 Data, this information should be included here.

6. Party 2 Disposition Requirements upon the termination or expiration of the Agreement

Instructions to the drafter; delete after completion of this section:
This section of this attachment should provide sufficient information such that each Party understands the Receiving Party's obligations with regards to the Party 2 Data upon the expiration or early termination of this Agreement. If the Receiving Party is permitted to link the Data with other data sets, be sure to include any special disposition requirements related to the linked data sets in this attachment.

7. For Party 2, send Data Select One to:

Name:
Email:
Address:

Phone:

Please note: ATTACHMENT 2 will be selected and sent to you by the ORA DUA team, this Attachment will vary based on data type and will not require any action on the PI/Das part as it is a read-alone page.

Attachment 3
Reciprocal Data Transfer and Use Agreement
Identification of Permitted Third Parties (if any)

For all purposes of this Agreement, the definition of "Third Party Personnel" checked below will pertain:

☐ "Third Party Personnel" means: None. No collaborators are permitted on the Project.

-OR-

☐ "Third Party Personnel" means as set forth below and agreed upon between the Parties:

Sample definition language for the drafter; delete if the first option is checked or after a final definition has been agreed between the Parties:

"Third Party Personnel" means: faculty, employees, fellows, or students of [NAME OF THIRD PARTY INSTITUTION], an academic institution, which institution (i) has agreed to collaborate in the Project, (ii) has faculty, employees, fellows, or students who have a need to use or provide a service in respect of the Data in connection with its collaboration in the Project, and (iii) has been made aware of the terms of this Agreement and agreed to comply, and to cause its personnel to comply, with such terms.

An alternative option for (iii): "has executed an agreement that is substantially similar to this Agreement"

Attachment 7

Attachment 7 is used for federal subawards that require the transfer of data as part of the Project.

PI completes
CWRU ORA DUA Team completes

Attachment 7
Human Subjects Data Transfer and Use Terms

Human Subjects Data ("Data") will be exchanged under this Subaward (check all that apply):

☐ From Subrecipient to PTE
☐ From PTE to Subrecipient

1. The Party providing the Data will be referred to as the "Provider," and the Party receiving the Data will be referred to as the "Recipient" as reflected above in this section.
2. The Data to be shared will be Select One
3. Provider authorizes Recipient to share the Data as may be required under the data sharing plan for this project, as may be required by the Data Sharing & Access section of this Agreement.
4. Upon completion of the Budget Period End Date Recipient shall retain or destroy the Data as instructed by the Provider; provided, however, that Recipient may retain one (1) archival copy of the Data.
5. Description of Data (Description is required if data is categorized as "Other" above; Optional otherwise):

Description of Data:

★ describe the data with specificity.

Note: this description should very closely match the one given to receive IRB approval (if applicable)

Please note: a 2nd page will populate based upon the type of data selected above.

Miscellaneous Institutional & Federal Data Policies & Procedures

The following pages contain CWRU Institutional Policies as well as Federal Database Policies & Procedures:

(1) Biospecimen Transfer Policy & Procedure
(2) Material Transfer Policy & Procedure
(3) NIAGADS Genomic Data Access Policies & Procedures
(4) NIAGADS Genomic Data Submission Policies & Procedures

Biospecimen Transfer Policy & Procedure

Biospecimen: A biospecimen means blood, serum, urine, saliva, other bodily fluid, bone marrow, cells, stool, or tissue samples/specimens collected from Human Subjects under an IRB Protocol. The term "Biospecimen" further includes, without limitation, any tangible material derived from such Biospecimens collected under the Protocol from Human Subjects, such as genes, gene fragments, gene sequences, proteins, protein fragments, protein sequences, DNA, RNA, and any subcellular structure, and their unmodified derivatives.

Biospecimen Transfer Agreement: The transfer of biospecimens and data between two organizations for use in a funded collaborative research project. Agreement language will be used in Attachment 7 subaward documents, funded SRAs, and any other funded agreement where the data transfer occurs with the inclusion of biospecimens.

- **CWRU Contact: ORA DUA OFFICE (Meghan Schane-Rambert/Monica Bradley)**

BTA PROCESS:

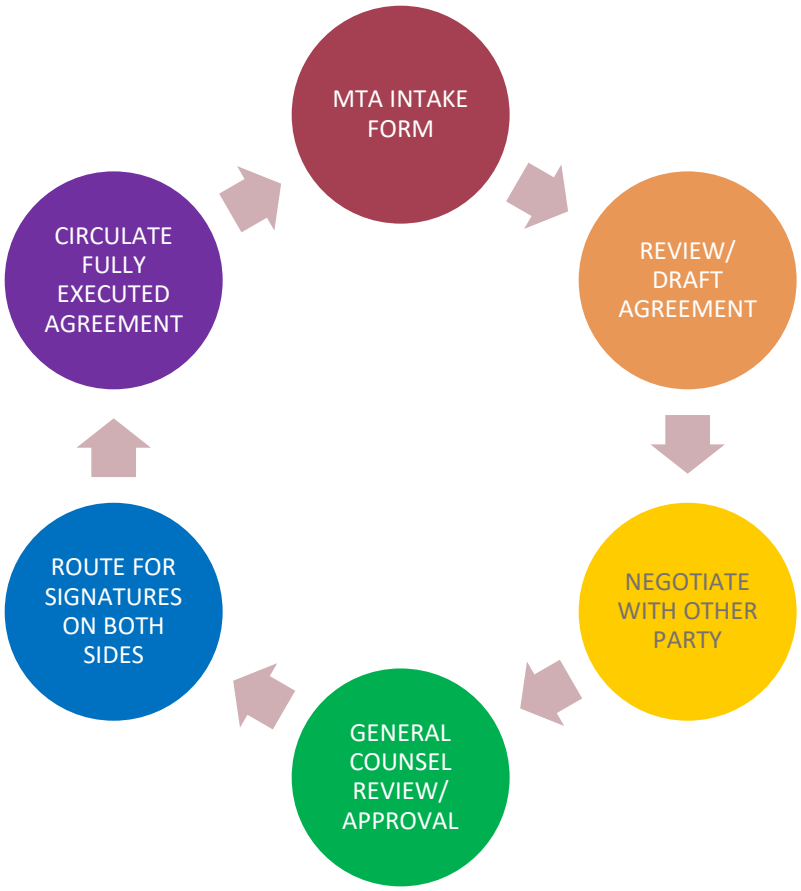
(1) Department Administrator (DA) or HUB personnel uploads SOW/Budget into Sparta.
(2) SOM OG&C and/or OSPA will ask the DA/PI "is the transfer of research data and/or biospecimens required as part of the research project?"
    a. If YES – DA/PI will EMT cwru-dua@case.edu with notice.
(3) ORA DUA will review the contract to determine if specific DUA terms & conditions will be required prior to execution of the contract.
    a. IF NO TERMS NEEDED: ORA DUA will EMT the DA/PI, SOM OG&C, and OSPA that "No additional DUA language is necessary. Please proceed."
    b. IF TERMS NEEDED: ORA DUA will Request PI/DA complete the DUA Request Form.
(4) ORA Contracts receives the DUA Request Form and reviews it.
    a. If this is a non-template situation, the ORA DUA team will insert the applicable DUA and BTA language into the agreement.
    b. If this is an Attachment 7 Subaward Template, the ORA DUA team will reach out to the DA/PI to help complete the template.
        i. The ORA DUA team will then add BTA terms and conditions.
(5) ORA DUA finalizes the terms and conditions.
    a. IF ATTACHMENT 7: ORA DUA will verify the template language, approve it, and upload the final completed template to Sparta (FP or IPAS) and EMT the DA/PI, SOM OG&C, and OSPA that "Attachment 7 has been reviewed and approved by the ORA DUA Team. Please add it to the subaward packet prior to submission."
    b. IF EMBEDDED (Non-SOM SRA or other Agreement): ORA DUA will verify the template language, approve it, and send a copy to the other party for partial execution by an Authorized Institutional Official.
        i. ORA DUA will then route to the appropriate Authorized Institutional Signing Official for CWRU signature and full execution (FE).
            1. ORA DUA will then provide a FE copy to the other party, the PI, and the DA.
    c. IF EMBEDDED (SOM SRA or other Agreement): ORA DUA will verify the template language, approve it, and upload the agreement to Sparta with an EMT to the DA/PI, SOM OG&C, and OSPA that "ORA DUA Team has reviewed and approved the inclusion of DUA terms into the SRA (or other named agreement). The updated SRA can be found in the logged comments below (or above). Please send to Sponsor for review"

Material Transfer Agreement Process

Material Transfer Agreement: A Material Transfer Agreement (MTA) is a contract that governs the transfer of tangible research materials between two organizations, when the recipient intends to use it for his or her own research purposes. If the transfer of material is part of a research agreement, then an MTA is NOT appropriate.

- **CWRU Contact**: **TTO OFFICE (Stacy Fening/Tyler Gray)**

(1) Department Administrator (DA) and/or PI reaches out to TTO that an MTA may be needed.
(2) TTO sends the MTA Intake Form to the PI/DA for completion.
(3) PI/DA returns completed MTA Intake Form to TTO.
(4) TTO will review and negotiate the MTA with the other party.
(5) TTO will seek OGC approval, if necessary.
(6) TTO will obtain Authorized Institutional Official signatures from CWRU and the other Party.
    a. The Institutional PI's may be required to sign the MTA, to indicate their acknowledgement to the terms and conditions of the Agreement. TTO will make this determination and obtain any necessary signatures.
(7) Upon receipt of all required signatures, TTO will then send the fully executed (FE) Agreement to the PI, DA, and any other pertinent parties.
(8) TTO will then upload all information into Sophia, the TTO Agreement Management System.



NIAGADS:
Genomic Data Access

Instructions for PIs Requesting Authorized Access to NIAGADS Datasets

Principal investigators (PIs) seeking access to NIAGADS datasets are urged to review the following information before initiating a data access request. By signing and appending the Data Use Certification Document it is understood that the Principal Investigator and the Institution will abide by the policies and standards set forth in that document.

ALL DOCUMENTS INCLUDING THE DATA USE CERTIFICATION DOCUMENT AND THOSE LISTED BELOW SHOULD BE UPLOADED IN PDF FORMAT TO WWW.NIAGADS.ORG/DATA/REQUEST. ANY QUESTIONS MAY BE DIRECTED TO THE NIAGADS DATA ACCESS ADMINISTRATOR AT NIAGADS@UPENN.EDU.

1. **Minimum Qualifications to Submit a NIAGADS Project Request as an Investigator**. Investigators must be permanent employees of their institution at a level equivalent to a tenure-track professor or senior scientist with responsibilities that most likely include laboratory administration and oversight. Laboratory staff and trainees such as graduate students, and postdoctoral fellows are not permitted to submit project requests.

2. **Supplemental Documentation. *The following four (4) REQUIRED documents must be uploaded with the pdf file during the NIAGADS application process in order for the Data Access Request to be considered complete.*** **THE FOLLOWING DOCS ALL NEED TO BE PROVIDED TO THE DUA OFFICE ALONG WITH YOUR DUA REQUEST FORM.**

   - **(1) IRB approval in compliance with the** NIH Genomics Data Sharing Policy (GDS)**. T**he Investigator must submit a current IRB approval for the proposed project that will use NIAGADS data.

   - **(2) Derived/Secondary Data Return Plan**. The Investigator must describe the derived/secondary data that will be returned to the NIA Genetics of Alzheimer's Disease Data Storage Site (NIAGADS): see Sample-Data-Return-NIAGADS (WORD).

   - **(3) National Institute of Aging (NIA) Genomic Data Sharing Plan.** This document must be signed by the Investigator and his/her Institutional Signing Official: see NIA Genomics Sharing Policy (WORD).

   - **(4) The NIAGADS Data Distribution Agreement.** This document must be signed by the Investigator and his/her Institutional Signing Official: see NIAGADS-DDA (PDF).

3. **Accessing Additional Datasets After Initial Approval.** Investigators who would like to access additional dataset(s) for use in an existing approved project should (1) revise the existing approved project request to include the new datasets and (2) update the Research Use Statement as appropriate. Investigators do not need to submit a new project request unless the dataset will be used for research outside of the scope of the approved Research Use Statement.

4. **Collection of Principal Investigator, Institutional and Contact Information.** Contact information for PIs and their designated institutional signing official will be provided in the Biosketch-Template.doc. Provide a biographical sketch in the new NIH Biosketch format: see NOT-OD-15-032.html for additional information.

5. **Research Use Statement.** The approval of project requests depends primarily on a carefully written Research Use Statement (2,200 characters max): see Research-Use-Template.doc. The statement should include the following components:
   - Objectives of the proposed research;
   - Study design;
   - Analysis plan, including the phenotypic characteristics that will be evaluated in association with genetic variants; Further project information will be gathered in the Supplemental-Information.pdf form.
   - Explanation of how the proposed research is consistent with the data use limitations for the requested dataset(s); and
   - Brief description of any planned collaboration with researchers at other institutions, including the name of the collaborator(s) and their institution(s).

The NIAGADS Data Use Committee will review the Research Use Statement to confirm that the proposed research is consistent with all applicable data use limitations for the requested dataset(s). An inconsistency between the proposed research and the applicable data use limitations, or insufficient detail to make this determination, is the most common reason for data requests to be rejected.

6. **Cloud Use Statement and Cloud Servicer Provider Information (if applicable).** Investigators who wish to use cloud computing for storage and analysis of NIAGADS data will need to indicate in their Data Access Request (DAR) that they are requesting permission to use cloud computing and identify the cloud service provider or providers that will be employed. They also will need to describe how the cloud computing service will be used to carry out their proposed research.

7. **Non-Technical Summary.** As part of the project request, investigators will provide a non-technical summary of their proposed research. If the project is approved, this statement will be publicly available for lay audiences to read the purpose and objectives of the research.
   - Non-technical summaries must be no more than 1,100 characters (including spaces).

8. **Staff and Collaborator Contact Information.** Provide the full legal names and contact information for internal collaborators (i.e., those employed at the PI's institution, but not directly supervised by the PI). Trainees and staff directly supervised by the PI, such as graduate students, postdoctoral fellows, and technicians, do not need to be listed on the project request. External collaborators should be listed in the external collaborator(s) section of the project request applications. Data exchange between all collaborators must be consistent with the NIH Security Best Practices for Controlled-Access Data Subject to the Genomic Data Sharing (GDS) Policy and GDS Policy:
   - **For External Collaborations:** To share NIAGADS data with collaborators outside of the PI's institution, the collaborators must submit a project request with (1) the same project title and (2) a Research Use Statement and Cloud Use Statement, if applicable, that references the collaboration (for smaller collaborations, the name and institution of the collaborating PI(s) or for larger efforts, the consortium name).

9. **Information Technology (IT) Director Contact Information.** Provide the full legal name and contact information for the IT Director, who is expected to be a senior IT official with the necessary expertise and authority to affirm the IT capacities at an academic institution, company, or other research entity. The IT Director is expected to have the authority and capacity to ensure that the NIH Security Best Practices for Controlled- Access Data Subject to the NIH GDS Policy and the institution's IT security requirements and policies are followed by the Approved Users.

To Request Access to this Database, you will follow the normal process of completing the DUA Request Form, however, you will need to upload or email CWRU-DUA@case.edu copies of IRB Approval Letter, Protocol Template, Consent Form, NIA Genomics Sharing Policy, & the NIAGADS Data Distribution Agreement.

NIAGADS:
Genomic Data SUBMISSION

(1) Department Administrator (DA) and/or PI completes the DUA Request Form.
   b. DA/PI will submit to ORA DUA the following:
      i. NIAGAD Genetics Sharing Plan; *and*
      ii. IRB Approval Letter, IRB Protocol Template, and IRB Consent Forms; *and*
      iii. Institutional Certificate Document; *and*
      iv. Phenotype Data File; *and*
         1. Tab-delimited plan text or excel file with data dictionary listing each variable and their description. Must include a column indicating the level of consent for each subject per the Institutional Certification Document.
      v. Pedigree Data File.
         1. Tab-delimited plaint text or excel file with the following standard pedigree file format:
            a. FAMID (family ID)
            b. SUBJID (subject ID)
            c. FATHER (father ID)
            d. MOTHER (mother ID)
            e. SEX (1 = male, 2 = female)
   c. If submitting Polymorphism Genotyping Data:
      i. DA/PI must also submit:
         1. (1) APOE Genotypes with description of the lab(s) that performed the genotyping and the genotyping methodology in README file format.
            a. NOTE: Computer files containing genotype of genetic mapping data should be in plain text files in the generic pedigree file format.
            b. NOTE: Data contributors need to use either PLINK (.ped and .map files) or MERLIN (.ped, .map, and .dat files).
         2. (2) Separate documentation clearly explaining the format used for the files submitted
            a. For PLINK pedigree format – including the URL to the definition of the file format is acceptable.
            b. For MERLIN pedigree forma – both a detailed definition of the fields and a URL to the format definition should be included.
         3. (3) Column in the files should be listed and explained.
         4. (4) Summary Statistics should be included.
         5. (5) System used to divide the genotyping into “plates” should also be explained.

(2) ORA DUA will review the documents and verify that IRB sharing consent has been given.
   a. ORA DUA will highlight the consent forms and/or protocol template to show where sharing has been permitted.

(3) ORA DUA will reach out to PI with any questions or comments.

(4) ORA DUA will obtain a CWRU Authorized Institutional Official Signature (**Joan Schenkel or Meghan Schane-Rambert**).

(5) ORA DUA will send all completed documents back to the PI and DA for their submission to the NIAGADS.

Thank you for learning about Data Use Agreements!

Our office is always available to assist you with your data transfer needs. Please reach out to CWRU-DUA@case.edu for assistance.