_____ and request that a link to your survey be sent so you may make edits to the survey.
Please note:This option is only available after you have submitted the form.

Contact Information

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.

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 subcontra 4.92 Tc 0.002 ccW.

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

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 rep.*[illegible]
   b. No [illegible]

Incoming Data Questions

1. Where do you intend to store and/or analyze the data? Check all that apply.
   -Secured Research Environment
   -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

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

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.