Data Use Agreement Request Form
6 21 2021

CWRU Data Use Request Form

Completion of the DUA Request Form is designed to assist investigators and ORA staff in:
- Determining when a DUA is required to receive data.
- Note: CWRU will not require a DUA if the provider of the data does not require a DUA.
- When IRB approval and a Data Security Plan is required.

General Questions

Q1.2 Name of Investigator Requesting Data Use Agreement
Q1.3 Name of person completing form if different from investigator
Q1.4 Department
Q1.5 School
Q1.6 Investigator CWRU NET ID
Q1.7 CWRU NET ID of person completing form if different from PI
Q1.8 Investigator Phone Number
Q1.9 Phone number of person completing form if different from investigator

Data Transfer Conditions

The purpose of this section of the form is to determine whether the transfer of data is allowable and if a DUA is required in order to transfer the data.

Q2.2 What is the investigator's role in the project?
- PI of the prime project
- PI of a subcontract to CWRU
- Key personnel on the proposal
- Collaborator without sponsored funding
- Other:

Q2.3 Does the CWRU investigator want to put restrictions on the use of the data being sent from CWRU?
- Yes
- No
- NA (Option for incoming DUAs)

Q2.4 Does the CWRU investigator intend to publish results from the data in the agreement?
- Yes
- No
Q2.5 Is this a collaborative project, where researchers from multiple institutions are involved in the research activities for the project?

This question is designed to gain information regarding the type of project for which the DUA is being requested to assist DUA staff in processing the DUA.

For example, a MPI grant where the CWRU investigator is one of the PIs, or where the CWRU investigator is the PI of the subcontract to CWRU or in the case of a funded grant with CCLCM where there is an agreement for funds to come CWRU for a portion of the work.)

- Yes
- No

Q2.6 If the data was initially received from, or derived from data received from a third party pursuant to a contract, does that contract place restrictions on the subsequent transfer of the data?

- Yes
- No

Source of the Data

Q4.2 Identify the source of the data.

- A fully executed sponsored project agreement.
- A collaborator with whom there is no funding and/or executed agreement/contract
- A commercial entity.
- A publicly available source. (Provide link)
- A pending award. (Indicate expected start date below) __________
- Controlled access data set (Identify below)
- Other (Describe below) ______________________________________________

Follow On Questions for Fully Executed Sponsored Agreement

Q5.1 What is the funding source?

- Federal Government
- State or Local Government
- Foundation
- Industry
- Other ______________________________________________

Q5.2 Who is the sponsor of the agreement?

Q5.3 What is the CON number? (This number is found on the bottom your CWRU notice of award in the Award ID field)

Q5.4 Attach the Notice of Grant Award or Grant/Contract Agreement from the sponsor.

Q5.5 Does the contract/sponsored research agreement prohibit data sharing?

- Yes
- No

Q5.6 If the data was collected pursuant to a contract/ sponsored research agreement, has the sponsor placed restrictions on the subsequent transfer of the data?

- Yes
- No
Q5.7 Is data sharing implied or included in the contract/sponsored research agreement?
- Yes
- No

Type of DUA
Q6.1 For the requested Data Transfer and Use Agreement (DTUA), the investigator is (please check one):
- Providing Data
- Receiving Data
- Both Providing and Receiving Data

Incoming Data Questions

Q7.1 What is the status of your data security plan?
- Approved (For approved Data Security Plans you will be asked to upload a copy or approval notification)
- Submitted and Pending Approval (Provide Date) ________________________
- Not Submitted (Provide estimated date of submission) ______

Q7.2 Where do you intend to store the data?

Q7.3 If the entity providing the data provided a draft DUA attach it to the DUA request form

Outgoing Data Questions

Q9.1 Where is your data currently being stored?
- Secured Research Environment
- UH REDCap
- CWRU REDCap Not SRE

Human Subjects or Not Human Subjects

Q10.1 Were the data to be transferred originally collected as part of a human subjects' research project?*  *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."
- Yes
- No
Q10.2 Are the data obtained from living individuals?
- Yes
- No

**Human Subjects** (Will appear if you respond yes to 10.1 or 10.2)

Q13.1 What type of data of human subjects data do you want to transfer?
- Protected Health Information (From a covered entity)
- Limited Data Set
- Personal data from someone in the EU or EEA
- Student Data
- Data being transferred across international borders
- Personally Identifiable Information
- De-Identified or Coded Date that may be considered Not Human Subject Data (Describe briefly)
- Other (Describe)

**IRB** (Will appear if you say yes to 10.1 or 10.2)

Q14.1 The data you are intending to receive or transfer is from human subjects research. Therefore IRB approval for data transfer or receipt is required. What is the status of your IRB? Please note: If the IRB protocol was approved at institution other than CWRU or UH a CWRU IRB approval may also be required.

- Approved (Provide IRB approval numbers below)
- Submitted to IRB (Provide submission date)
- Other (Describe)

Q14.2 Which IRB will review/approve or has reviewed/approved your IRB protocol?
- CWRU IRB
- UH IRB
- Other (Name IRB below)

**IRB Approved** (Will appear if you respond yes to IRB approved)

Q15.1 Does the informed consent form that subjects signed upon entering the study or the relevant IRB protocol, permit disclosure for the contemplated DUA purpose?
- Yes
- No

Q15.2 Upload a copy of your approved IRB protocol and consent form.
**Limited Data Set Question** (Will appear if you indicate your data is a limited data set)

Q16.1 Limited Data Set
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

**Non-Human Subjects Determination** (Will appear if you respond no 10.1 and 10.2)

Q17.1 Responses to the questions below will enable the DUA to confirm that the data you are intending to send or receive is not considered human subjects data.

Q17.2 Do any of the collaborators have access to the identifiers?

- Yes
- No

Q17.3 Are the information:

- Unidentifiable data obtained from a commercial provider; or
- Unidentifiable data obtained from a provider that is prohibited from releasing identifiers by established regulations or policies

- Yes
- No

Q17.4 Were the information collected specifically for the proposed research through an interaction or intervention with living individuals by CWRU investigators or other collaborators?

- Yes
- No

Q17.5 Can the recipient link the data directly to identifiable private information of living individuals?

- Yes
- No
Q17.6 Can the *provider* link the data **directly** to identifiable private information of living individuals?
- Yes
- No

Q17.7 Does the data *provider* meet the definition of an “investigator” in the recipient's research?
- Yes, the provider is collaborating with CWRU faculty on the research project.
- No, the provider is solely providing the data.

Q17.8 Are the data provided with a code linking them to identifiable private information of living individuals?
- Yes
- No

Q17.9 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.
- Yes
- No

**Outside Organization Information**

Q11.1 Name of Organization CWRU is providing data to or receiving data from:
Q11.2 Contact Name of Person
Q11.3 Contact Title
Q11.4 Contact Phone
Q11.5 Contract Email
Q11.6 Role of Contact