Material Transfer Agreement and Data Use Agreement Request Form Questions

Please familiarize yourself with all questions prior to beginning the MTA-DUA Request Form.

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.*

Mandatory Questions are notated with an Asterisk*.

If you discover you need to make corrections/revisions to sections of the MTA-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. Please note: This option is only available after you have submitted the form.

CWRU INFORMATION

1. Name of the CWRU Principal Investigator requesting the MTA or DUA*
2. CWRU Principal Investigator's Title*
3. CWRU Principal Investigator's email address*
4. CWRU Principal Investigator's phone number*
5. Name of the person completing the form, if different from the Principal Investigator
6. Email address of person completing the form, if different from the Principal Investigator
7. Phone number of person completing the form, if different from the Investigator
8. CWRU Department*
9. CWRU School*
    - School of Engineering
    - College of Arts and Sciences
    - Frances Payne Bolton School of Nursing
    - Jack, Joseph, and Morton Mandel School of Applied Social Sciences
    - School of Dental Medicine
    - School of Law
    - School of Medicine
    - Weatherhead School of Management
    - University General (UGEN)
10. Will this transfer take place as part of a funded project (e.g. collaborative grant, subaward, sponsored research agreement, etc.) between CWRU and another Organization?*
    - Yes
    - No

Questions 11 and 12 will appear if you indicate that your agreement is part of a funded project.

11. Provide the specific Project Title, Project Description and Funding Proposal Number (from Sparta).*
12. What is the investigator's role in the project for which the transfer or access is being requested?
    - Lead PI of the funded project
    - PI of a subcontract to CWRU
    - Co-investigator on a project

OUTSIDE ORGANIZATION INFORMATION

1. Name of the Organization sending or receiving Materials or Data*
2. Name of Investigator at the Organization*
3. Organization Investigator's Title
4. Organization Investigator's email address*
5. Organization Address (include city, state and country)*
6. Organization Administrative point of contract, title and email
7. Is the Organization located outside of the United States?*
    - Yes
    - No

Questions 8 and 9 will appear if you indicate the Outside Organization is located outside of the United States.

8. If the Organization is located outside of the United States, provide a comprehensive statement from you explaining the critical value and rationale behind the proposed relationship with the foreign institution, entity, or person. This statement should clearly articulate the benefits and necessity of the collaboration.*
9. If the Organization is located outside of the United States, please provide an email from your department chair explicitly approving entry into the agreement.*

HUMAN SUBJECT DETERMINATION

1. Is the material or data of human origin?*
    - Yes
    - No
    - I'm not sure (check if you are unsure if your material or data is of human origin or if your use may be considered non-human subjects research)

INSTITUTIONAL REVIEW BOARD (IRB) QUESTIONS

IRB Questions will appear if your material or data is of human origin.

1. The Materials or Data you are intending to access, receive or transfer may require oversight for research involving human subjects. Therefore, IRB approval may be required. Please chose the answer below that best describes the status of your IRB approval.*
   PLEASE NOTE: If IRB oversight is required, no DUA or MTA will be executed until IRB Approval is received by our office.
    - Approved (Provide IRB approval numbers): _____
    - Submitted to IRB (Provide submission date): _____
    - Not yet submitted to IRB. The approximate planned submission date is: _____
    - I do not believe the activities with this data are human subjects research.

Questions 2-7 will appear if you indicate you have IRB approval or will be applying for IRB approval.

2. Which IRB will review/approve or has reviewed/approved your IRB protocol?*
    - CWRU IRB
    - UH IRB
    - Other (Name IRB below) _____
3. Describe your role in the approved Protocol:*
    - I am the Principal Investigator
    - I am not the Principal Investigator, but I am named in the Protocol. Please explain: _____
    - I am not named in the Protocol. Please explain your role in the project: _____
4. **UPLOAD** a copy of the IRB protocol.
5. **UPLOAD** a copy of the IRB approval letter.

6. **UPLOAD** a copy of the Consent Form(s).
7. Does the informed consent form or the relevant IRB protocol, permit disclosure of information for the contemplated research purpose?
    - Yes. Indicate Page Number: _____
    - No

IRB SCREENER QUESTIONS

IRB Screener Questions will appear if you indicate your materials or data are not of human origin, if you are unsure, or if you indicate you do not believe the data or materials are human subjects research.

THE FOLLOWING QUESTIONS WILL HELP US DETERMINE IF YOU NEED INSTITUTIONAL REVIEW BOARD APPROVAL OR IF YOUR RESEARCH WILL FALL UNDER THE EXEMPT OR NOT HUMAN RESEARCH DETERMINATION CATEGORIES.

1. Were the data/materials/biospecimens obtained from living individuals?*
    - Yes
    - No
2. For what purpose were the data/materials/biospecimens originally collected?*
    - Clinical/Discarded tissue
    - Research
    - Other: _____
3. If collected for research purposes, were the data/materials/biospecimens collected specifically for the work you are doing? (Answer “yes” if your analysis is part of the original aims of the study for which the specimens were collected. Answer “no” if your work is secondary analysis that is different from the original study).*
    - Yes
    - No
    - Not applicable
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?*

    NOTE: 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
5. If you are sending data/materials/biospecimens outside CWRU, in what form will they be sent?*
    - De-identified or fully anonymized: data/materials/biospecimens have been stripped of all identifying information and there is no way that anyone 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). This includes, but is not limited to, human cells lines obtained from a commercial provider, human cell lines about which all information has been published, and unidentifiable biospecimens obtained from a commercial provider.
    - Coded: identifying information that allows you 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, allowing the data to be linked back to an individual.
    - Identifiable: data/materials/biospecimens with identifiers that would allow a researcher to identify an individual to whom the data pertains.
6. Will the research data generated from use of the transferred data/materials/biospecimens 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).
    - Yes
    - No
7. Does the data include whole genome sequence data or the generation of whole genome sequence data?*
    - Yes
    - No
8. Are the data/materials/biospecimens being provided with personally identifiable information?*
    - Yes
    - No
9. Can the *provider* link the data **directly** to identifiable private information of living individuals?*
    - Yes
    - No
10. Does the *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 or materials.*
    - Yes, the provider is collaborating with CWRU faculty on the research project.
    - No, the provider is solely providing the data.
11. Is 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
    - N/A
12. 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
13. Do any of the collaborators have access to the identifiers?*
    - Yes
    - No
14. Are the data/materials/biospecimens being provided by a covered entity?*
    (A covered entity is defined under the HIPAA Privacy Rule as (1) health plans, (2) health care clearinghouses, and (3) health care providers who electronically transmit any health information in connection with transactions, such as billing and payment for services or insurance coverage.)
    - Yes
    - No
    - Unknown
15. If the provider is solely providing the data/materials/biospecimens, are the materials provided with a code linking them to identifiable private information from living individuals?*
    - Yes
    - No

16. If the materials are coded, can you readily ascertain the identities of the individuals to whom the data pertain? (Do you have access to the master list, linking the code to the identifiable information?)
    - Yes
    - No

AGREEMENT SPECIFIC QUESTIONS

Your answer to this section will determine the branching logic for your specific agreement needs.

1. What type of agreement are you requesting? (Check all that apply.)*
    - Material Transfer Agreement
    - Data Use/Transfer Agreement
    - A Renewal of an existing agreement
    - An Amendment to an existing agreement

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 or amendment if provided by Organization.
2. **UPLOAD** the original DUA or MTA between CWRU and Organization.
3. Describe any the conditions of the agreement that have changed, reason for amendment or indicate if this is a renewal only request.*
    - This is a renewal or amendment request and the following conditions have changed: _____

MATERIAL TRANSFER INFORMATION

This section will appear if you indicate that you are requesting an agreement to transfer Material or Material and Data.

1. Are you Sending or Receiving Materials? (If you are sending and receiving Materials, please choose "both".)
   - Sending
   - Receiving
   - Both
2. **UPLOAD** any Agreement or other documentation provided by the Organization here:
3. Shipping address for Recipient (if different from institutional address.)
4. What is the specific (scientific) FULL NAME of the Material that is being transferred?
5. Which of the following categories best describes the Material (check all that apply.)
   - Live animal
   - Plasmid
   - Vector
   - Bacteria
   - Virus
   - Genetic material
   - Cell line
   - Human embryonic stem cell line
   - Human tissue, blood, etc.
   - Animal tissue
   - Chemical compound
   - Software
   - Database
   - Gene chips
   - Medical device
   - Other - please describe: _____
6. If receiving, please briefly describe how the Material will be used in your research, including the purpose or function of the Material.
7. If you are transferring any hazardous materials, we will contact the appropriate office for an ancillary review prior to execution of a Material Transfer Agreement. You will be notified with additional instructions and/or approval as necessary. Please indicate if the Material is considered any of the following hazardous materials:
   - Radioactive
   - Select Agents and Toxins, including exempt quantities. (Biological agents and toxins that the U.S. Departments of Health and Human Services (HHS) and Agriculture (USDA) have determined to have the potential to pose a severe threat to public, animal, and plant health and safety.)
   - Infectious agents (bacteria, viruses, fungi, etc.)
   - BSL-3 agents
   - Recombinant/synthetic nucleic acids
   - Human pluripotent stem cells
   - Other _____
   - The Material is not hazardous
8. Will you be providing or receiving any unpublished or confidential information with the Material?
   - Yes
   - No
   - Unknown at this time.
9. Do you anticipate any new inventions will be developed from the use of the Material? (Check all that apply)
   - Yes - CWRU Inventions only
   - Yes - Co-Inventorship or Joint-Inventions

- Yes - Organization Inventions
- No

10. Do you intend to collaborate with the Organization? If so, please describe.
11. Is the Material available from another source or is it commercially available for purchase?
    - Yes
    - No
    - Unknown
12. Will the Material be used in research to further develop an invention that has already been disclosed to CWRU Technology Transfer Office by you or someone else?
    - Yes - Please provide reference number and inventor _____
    - No
13. Where was the originally Material generated? (Specify in your lab or identify the origin of the Material.)
    - CWRU Lab
    - The Material was generated at another institution. Please specify: _____
    - The Material was purchased from a commercial entity. Please specify: _____
    - Other _____

Questions 15-18 will appear if you indicate that you are sending Materials.

14. Is the Material the subject of any other agreement (MTA, license, sponsored research, or other)?
    - Material Transfer Agreement
    - License
    - Purchase Order with/without Terms and Conditions
    - Other. Please specify: _____
    - Unknown
15. If the Material is the subject of any other agreement, license, purchase order, etc., please **UPLOAD** it here.
16. If the Material incorporates third-party material or is it a modification of material received from a third party, please provide the name of the third-party material, name of the third-party provider organization, and indicate whether you have written permission to transfer the material.
17. Is there a specific length of time you would like to permit the Recipient to complete the research and/or modify the material?
    - No time restriction
    - 1 year
    - 2 years
    - 3 years
    - 4 years
    - 5 years

Question 19 will appear if you indicate that you are sending animals.

18. If this is a transfer of animals, can the animals be bred, cross-bred or neither?
    - The animals can be bred.
    - The animals can be cross-bred.
    - The animals may NOT be bred.
    - Not Applicable.
19. If the sending institution is charging a fee to cover the packaging and delivery, enter it here or enter N/A.
20. PLEASE NOTE IF THERE ARE ANY SPECIAL INSTRUCTIONS YOU WOULD LIKE INCLUDED IN THE MTA.

DATA TRANSFER INFORMATION

This section will appear if you indicate that you are requesting an agreement to transfer Data or Material and Data.

1. For the requested Data Use Agreement, the CWRU Investigator is (please check one):
   - Providing Data
   - Receiving Data
   - Providing and Receiving Data (Reciprocal)
   - Accessing Data (Choose this option when you are going to access a portal and will NOT download the data.)
2. Provide a DETAILED description of the data you intend to transfer, receive, or access.
3. Provide a brief description of your intended use of the data and the project.
4. Was the data obtained from living individuals?
   - Yes
   - No

Question 5 will appear if you indicate that the data was obtained from living individuals.

5. Which of the following most likely applies to the human subjects' data you want to transfer? (Check all options that apply.)
   - 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 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).
   - 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.
   - Genetic Data
   - Other (Describe below) _____

Questions 6 and 7 will appear if you indicate that you are requesting a limited data set.

6. Describe the limited data set.
7. 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

8. **UPLOAD** the Data Use Agreement, Data Transfer Agreement, Data Access Agreement, Data Licensing Agreement if provided by the other party.

DATA SECURITY

Questions 1 and 2 will appear if you indicate that you are receiving or accessing Data.

1. Where do you intend to store, access and 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 REDCap
   - UH REDCap
   - CWRU Qualtrics
   - CWRU Box
   - CWRU Google Drive
   - CWRU Microsoft Sharepoint
   - CWRU High Performance Computing Cluster
   - CWRU Research Virtual Machine
   - Departmental Server
   - Amazon Web Service
   - Google Cloud Platform
   - CWRU Laptop
   - CWRU Desktop
   - Other - Please describe below:_____
2. Who will be monitoring the data?
   - UTech
   - Local/Department Personnel (provide name below): _____
3. **UPLOAD** a copy of your approved security plan or an email from UTech indicating approval of your data storage and security plan, if applicable.

SIGNATURE*

You will be asked to sign the form on the final page of the Form. By signing the form, the person completing this form certifies that all information is accurate and up to date.

PLEASE NOTE: When you click the Right Arrow below, you will submit your MTA-DUA Request Form. If you are not ready to submit, please use the Left Arrow to return to the previous page.

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