Data Use Agreements

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For DUA requests or more information about MTAs, contact the general inbox at
ottmta@emory.edu

- **Data Use Agreement (DUA)**—also referred to as data sharing agreements or data use licenses or data transfer agreements—are documents that describe what data are being shared, for what purpose, for how long, and any access restrictions or security protocols that must be followed by the recipient of the data.

Why is a DUA needed?

- Human subject data protected by law or policy (Ex: Health Insurance Portability and Accountability Act (HIPAA) , Common Rule or Family Educational Rights and Privacy Act (FERPA)
- Provider institution policies
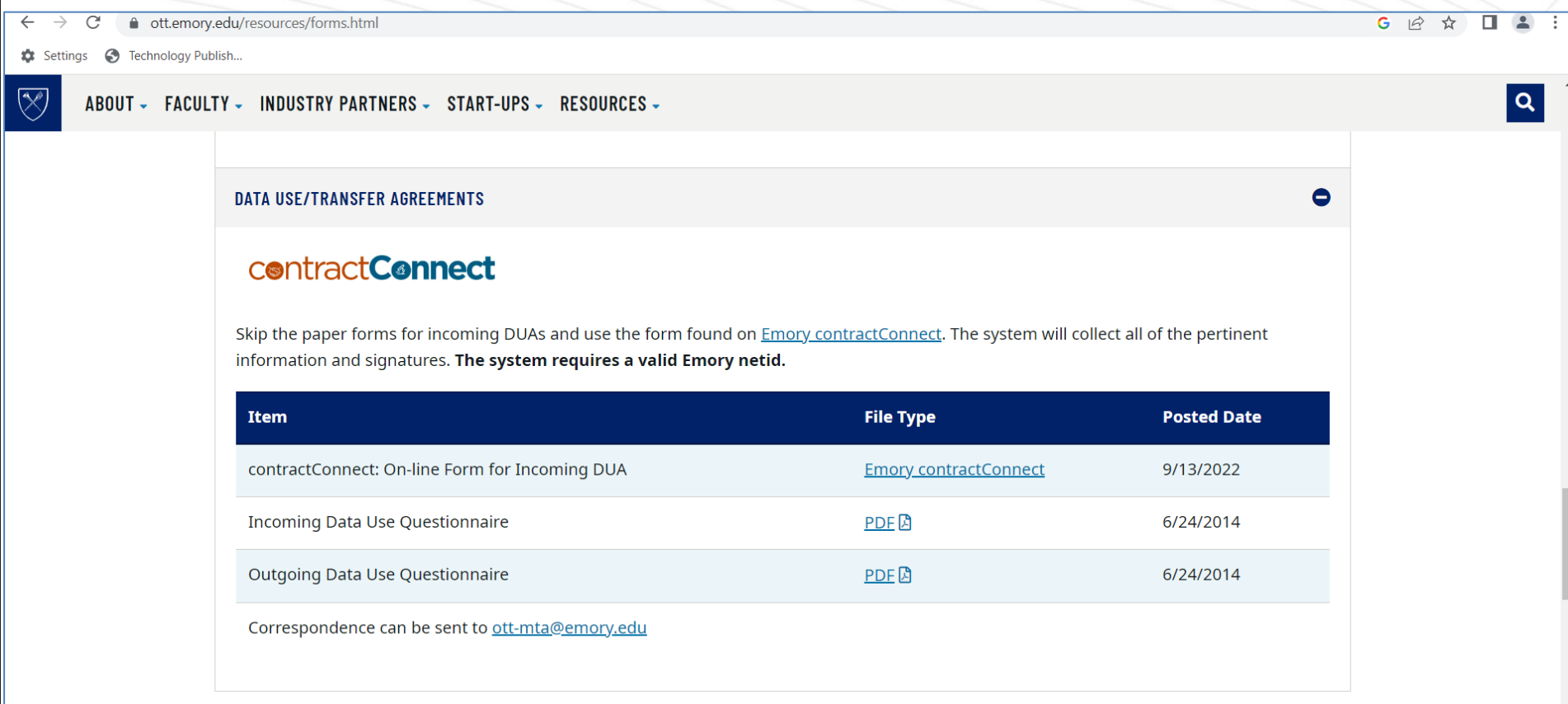- Contractual Restrictions
- Proprietary data

Requirements for a Data Use Agreement

The required elements of a Data Use Agreement under HIPAA are also applicable to DUAs for other types of data and include (but are not limited to) the following:

1. Establish the permitted uses and disclosures of the data by the recipient;

2. Establish who is permitted to use or receive the data;

3. Provide that the data recipient will:

   a. Not use or disclose data other than as permitted;

   b. Use appropriate safeguards to prevent use or disclosure of the data;

   c. Report to the entity providing the data any use or disclosure not permitted by the agreement

   d. Ensure that any agents of the data recipient agree to the same restrictions and conditions as the data recipient; and

   e. Not identify the information or contact any individuals.

If the dataset includes sensitive health information such as HIV/AIDS, STDs, mental health and/or substance abuse, as this information is subject to additional federal and state legal requirements.

DUA management at OTT (https://www.ott.emory.edu/resources/forms.html)

*Bi-lateral Data Use Agreements: Submit the agreement to ott-mta@emory.edu.

*The transfer of data for a pending grant/contract that is in the process of being executed, send to osp-contracts@listserv.cc.emory.edu

INCOMING DATA TRANSFER AGREEMENT QUESTIONNAIRE

Certain information is required to process and execute your Data Transfer Agreement (DTA). To avoid any delays with your DTA, please complete all of the fields below.

Please forward by email (1) an electronic WORD copy of the DTA, (2) the completed questionnaire, and (3) any relevant correspondence to OTT-MTA@emory.edu.

Principal Investigator Information:
(The Principal Investigator is the Emory faculty member/senior investigator under whose direction the research with the materials will be conducted)

Name of recipient scientist:	
Phone:	Email address:
Department :	Emory Employee ID: (Please do not provide SSN)
Mailing address:	

Provider Information:

Name of providing institution or company:	
Name of providing scientist:	
Phone:	Email address:
Name of DTA/DUA specialist at providing institution:	
Phone:	Email address:
Mailing address:	

Funding Information:

Please indicate the funding source and grant/contract number for this study:

Data Information:

1. Please describe the data, including whether it will contain identifiers or is **fully de-identified** under HIPAA:

2. Provide a brief but complete description of the proposed research with the Data, including the name of the research study:

3. Will the incoming Data be used in conjunction with:
(a) data generated by Emory under a sponsored agreement or (b) data received from a third party institution?

   OR Will the incoming Data be **transferred** by Emory to another institution?
   ☐ Yes   ☐ No

   If yes, please identify the third party or sponsor and briefly describe how the incoming Data will be shared and/or combined with other data?

4. Has applicable IRB approval been obtained for the research you will conduct using the Data?
   ☐ Yes   ☐ No

5. Have you read, and do you understand and agree to comply with any and all data security parameters that are contained in the DTA?
   ☐ Yes   ☐ No

6. Do you anticipate any new inventions will be developed from the use of the Data?
   ☐ Yes   ☐ No

   If yes, please describe the anticipated inventions or discovery (e.g., will invention incorporate the Data, be an entirely new product, new use of the existing product, cell line etc.?)

DTA Checklist:

☐	Advise Emory's Contract Specialist of any time-sensitive / urgent deadlines for this DTA.
☐	Send electronic *.doc* copy of the DTA template to: OTT-MTA@emory.edu
☐	Send **signed** copy of (this) Incoming Data Questionnaire to: OTT-MTA@emory.edu

I certify that all the information provided above is accurate and up to date.

Signature of the Principal Investigator: (who is the grant recipient)

1

2

Agreement Type: Outgoing Data Use Agreement (DUA)

This internal questionnaire will be used to determine the details of the contract we need to put in place with your collaborator for the sole purpose of you sharing data with them.

Project Title: _____

Provider Scientist (*The Provider Scientist is the Emory faculty member/senior investigator under whose direction the Data will be provided.*)
Name: _____
Phone: _____
Email address: _____
School/Center (Research location): _____

Recipient Institution (*The institution/company to which the Data is being provided.*)
Institution name: _____
Recipient Institution mailing address: _____

Recipient Scientist name: _____
Phone: _____
Email address: _____
Address: _____

Recipient Institution contracting officer name (if known): _____
Phone: _____
Email address: _____

Provide a description of the Data to be provided to the Recipient Institution.

Provide a description of the Project to be conducted by the Recipient Institution Scientist.

Data Transfer Information

1. Indicate the reason this data use agreement is being requested.

☐ To transfer data related to an executed funding agreement or clinical agreement. If selected, indicate the EPEX number.

☐ To transfer data for a pending grant/contract that is in the process of being executed. If selected, indicate the EPEX number

☐ To collaborate with another Investigator where there is no funding and/or executed agreement/contract.

☐ Other If selected, provide details

2. Does anyone outside of Recipient Institution Scientist's research group or Recipient Institution need access to this data for the designated project?

☐ No

☐ Yes, provide details

3. Is the Data initially received from, or derived from data received from a third party pursuant to a contract? Ex: Children's Healthcare of Atlanta, VA Atlanta Health Care, Grady Memorial Hospital or any other outside entity.

☐ No

☐ Yes, provide details

4. Does Provider Scientist (Emory faculty/scientist) want to request reimbursement for any costs associated with the assembly, preparation, compilation, or transfer of the Data to the Recipient Scientist?

☐ No

☐ Yes, provide details

5. Is the Data to be transferred originally collected as part of a human subjects' research project conducted by Emory personnel? *

*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."

☐ **No, provide details** below regarding the Non-Human Subjects Data (e.g., animal data, proprietary information, etc.) then **Skip to question #5(e).**

☐ **Yes,** check the box below that applies to the human subjects' data you want to transfer? **Check all that apply.**

5(a). ☐ **This is Protected Health Information.**
Protected Health Information is identifiable information about an individual's past, present or future physical or mental health condition, health care, or payment for health care that is created by a Covered Entity. *

* Covered Entity is a health plan, health care provider, or health care clearinghouse that transmits any health information in electronic form in connection with a transaction covered under HIPAA regulations. Such a transaction is one that involves transmitting identifiable health information in electronic format in connection with billing an insurance company or government benefits program (e.g., Medicare) for health care treatment.

If selected, where within Emory the Data coming from?
☐ Emory Healthcare
☐ Emory University Student Health Service
☐ Emory University School of Medicine
☐ Emory Autism Center
☐ Other, Provide details (EX: SON, RSPH, ECAS)

5(b). ☐ **This is a Limited Data Set that does not include any of the following identifiers.** (*A limited data set is described as health information that excludes certain, listed direct identifiers (see below) but that may include city; state; ZIP Code; elements of date; and other numbers, characteristics, or codes not listed as direct identifiers. The direct identifiers listed in the Privacy Rule's limited data set provisions apply both to information about the individual and to information about the individual's*

relatives, employers, or household members. All of the following identifiers must be removed from health information if the data are to qualify as a limited data set)

1. Names.
2. Postal address information, other than town or city, state, and ZIP Code.
3. Telephone numbers.
4. Fax numbers.
5. Electronic mail addresses.
6. Social security numbers.
7. Medical record numbers.
8. Health plan beneficiary numbers.
9. Account numbers.
10. Certificate/license numbers.
11. Vehicle identifiers and serial numbers, including license plate numbers.
12. Device identifiers and serial numbers.
13. Web universal resource locators (URLs).
14. Internet protocol (IP) address numbers.
15. Biometric identifiers, including fingerprints and voiceprints.
16. Full-face photographic images and any comparable images.

If selected, where within Emory the Data coming from?
☐ Emory Healthcare
☐ Emory University Student Health Service
☐ Emory University School of Medicine
☐ Emory Autism Center
☐ Other, Provide details (EX: SON, RSPH, ECAS)

5(c). ☐ **This is a fully De-identified Data Set.**
(*In order to qualify as fully de-identified, all of the 18 identifiers below that could be used to identify the individual or the individual's relatives, employers, or household members must be removed and also there must have been no actual knowledge that the remaining information could be used alone or in combination with other information to identify the individual who is the subject of the information*)

1. Names.
2. All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP Code, and their equivalent geographical codes, 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.
b. The initial three digits of a ZIP Code for all such geographic units containing 20,000 or fewer people are changed to 000.
3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all

elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older.

4. Telephone numbers.
5. Facsimile numbers.
6. Electronic mail addresses.
7. Social security numbers.
8. Medical record numbers.
9. Health plan beneficiary numbers.
10. Account numbers.
11. Certificate/license numbers.
12. Vehicle identifiers and serial numbers, including license plate numbers.
13. Device identifiers and serial numbers.
14. Web universal resource locators (URLs).
15. Internet protocol (IP) address numbers.
16. Biometric identifiers, including fingerprints and voiceprints.
17. Full-face photographic images and any comparable images.
18. Any other unique identifying number, characteristic, or code, unless otherwise permitted by the Privacy Rule for re-identification.

The following link provides guidance regarding methods for de-identification:
http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/De-identification/guidance.html#standard

If selected, where within Emory the Data coming from?
☐ Emory Healthcare
☐ Emory University Student Health Service
☐ Emory University School of Medicine
☐ Emory Autism Center
☐ Other, Provide details (EX: SON, RSPH, ECAS)

5 (d). ☐ **This is Identifiable Health Information.**
(*Identifiable health information pertaining to an individual that is not subject to the Health Insurance Portability and Accountability Act (HIPAA) or the Family Educational Rights and Privacy Act (FERPA)*)

IRB Information for 5(a), 5(b), 5(c), & 5(d)
The data you are intending to transfer may require oversight for research involving human subjects. Therefore, IRB approval for this data transfer may be required. What is the status of your IRB protocol? 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
If selected, please submit a copy of the Emory IRB's on-Human Subjects Research Determination Electronic Form (found on Emory IRB website) that indicates whether an IRB submission is needed or not.

Which IRB is handling the protocol that will collect/has collected the Data
☐ Emory IRB
☐ Other, IRB name:
☐ NA

Approved IRB
Include a copy of your IRB protocol template.
Include a copy of your IRB approval letter.

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?
☐ No
☐ Yes, provide details
Upload a copy of your consent form.

5 (e). ☐ If you checked NO under 5, provide details regarding the non-Human Subjects Data (e.g., animal data, proprietary information, etc.)

6. If the data transfer will be to a for-profit entity, please describe the Providing Scientist's expectations for deliverables (EX: Publication, monetary compensation etc.) in return for transfer of the Data.

I certify that all the information provided above is accurate and up to date.

Signature of Provider Scientist: _____
Printed Name of Provider Scientist: _____
Date: _____

Classification of Data

- **Protected Health Information (HIPAA)**

    - Protected Health Information is identifiable information about an individual's past, present or future physical or mental health condition, health care, or payment for health care that is created by a Covered Entity. *

    Covered Entity is a health plan, health care provider, or health care clearinghouse that transmits any health information in electronic form in connection with a transaction covered under HIPAA regulations. Such a transaction is one that involves transmitting identifiable health information in electronic format in connection with billing an insurance company or government benefits program (e.g., Medicare) for health care treatment.

Emory University is a "Hybrid Covered Entity"...some of its units are subject to HIPAA regulations and others are not.   Those units that are subject to HIPAA are called "Covered Components" [Emory School of Medicine, Emory Autism Center, Emory University Student Health Service]

Note: Emory Healthcare is a separate covered entity

Classification of Data (Cont)

- **Limited Data Set (HIPAA)**

  "A limited data set is protected health information that excludes the following direct identifiers of the individual or of relatives, employers, or household members of the individual:

  1. Names
  2. Postal address information (but not city/town, state and zip code)
  3. Telephone numbers
  4. Fax numbers
  5. Email addresses
  6. Social security numbers
  7. Medical record numbers
  8. Health plan beneficiary numbers
  9. Account Numbers
  10. Certificate/license numbers
  11. Vehicle identifiers and serial numbers
  12. Device identifiers and serial numbers
  13. URLs
  14. IP addresses
  15. Biometric identifiers, including finger and voice prints
  16. Full face photographic images and any comparable images"

Classification of Data (Cont)

- **Fully De-identified Data Set (HIPAA)**

    - *In order to qualify as fully de-identified, all of the 18 identifiers that could be used to identify the individual or the individual's relatives, employers, or household members must be removed and also there must have been no actual knowledge that the remaining information could be used alone or in combination with other information to identify the individual who is the subject of the information*)

- The following link provides guidance regarding methods for de-identification: http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/De-identification/guidance.html#standard

Classification of Data (Cont)

- **Identifiable Health Information (Subjected to Emory Policy)**

"…any information pertaining to the health of an individual that is identifiable, and is accessed, retained, used, or disclosed in any form or medium by or on behalf of the Institution. Identifiable Health Information does not include information subject to the Health Insurance Portability and Accountability Act (HIPAA) or Family Educational Rights and Privacy Act (FERPA).

(Emory University Identifiable Health Information Policy, https://emory.ellucid.com/documents/view/19778)

The EU GDPR and other International Privacy Laws

- HIPAA is irrelevant to international privacy laws.

- They apply to personal data transferred FROM the European Union (or the United Kingdom, or other country or economic area).

- They impose requirements on organizations located in those countries to ensure that the data they transfer to the United States is protected according to EU laws.