FDP DATA TRANSFER AND USE AGREEMENT (DTUA) TEMPLATE
FREQUENTLY ASKED QUESTIONS

Introduction
These FAQs, created by the DTUA Working Group under the direction of the FDP Data Stewardship and Contracts Subcommittees, pertain to the FDP Data Transfer and Use Agreement (DTUA) templates/samples and their applicable attachments.

Categories of Questions (click hyperlink below):

- General Questions
- Guidance on Selecting Versions of Attachment 2
- Guidance for Transferring Personally Identifiable Information

Questions regarding this FAQ document can be directed to the DTUA Working Group Co-Chairs at DTUA@thefdp.org.

General Questions

1. For what data types/sharing scenarios have the templates/samples been created?

The DTUA templates and samples currently developed are intended to facilitate the transfer/sharing of research data between U.S.-based nonprofit and/or governmental organizations for research or public health purposes. The DTUA templates/samples are designed to be flexible enough for use in sharing multiple different types of data which may be subject to differing requirements under law and/or regulation. Currently, the FDP has finalized and published the following documents for various data-sharing scenarios on the Data Stewardship and Contracts subcommittee website pages:

	Document title	Purpose
Templates (should not be changed; must remove FDP branding if changed)	One-Way DTUA Template	One-way sharing of data between 2 parties; recipient may be granted the right to share datawith permitted third parties. See question 8 for more information about permitted third parties.
	Reciprocal DTUA Template	Two-way sharing of data between 2 parties; recipient may be granted the right to share data with permitted third parties See question 8 for more information about permitted third parties.
	DTUA Amendment Template	Modifying basic elements of an ongoing DTUA (extension, change of Attachment 2, etc.). Should not be used to change the template type or other major changes. See question 15 for more information.
Samples (changes may be made; must remove FDP branding if changed - See questions 4 and 9 for more information.)	Collaborative DTUA sample	Project involves more than 2 parties. Data may flow in multiple directions.
	DTUA Sample For Scientists Transferring Institutions	This Sample may be used to transfer data with a PI who permanently moves to a new institution.
	Public Health Emergency (PHE) DTUA Sample	Streamlined DTUA for 1-way sharing of data for PHE-specific purposes during declared federal public health emergencies only. May be used for public health purposes as well as research. Use of this sample in unmodified form will greatly facilitate researchers rapid access to data.
Attachment 2 (Except for the PHE sample, there must be at least 1 Attachment 2 attached to DTUA to convey appropriate data protection terms based on type of data shared)	De-Identified Human Subjects Data	Attach this to the DTUA when sharing human subjects data that do not contain identifiers.
	Limited Data Set	Attach this to the DTUA when sharing data that meet the HIPAA definition of a Limited Data Set (LDS).
	Personally Identifiable Information - Common Rule Only	Attach this to the DTUA when sharing data that contain identifiers and the data collection was governed by the Common Rule and not covered by HIPAA, FERPA, or other similar regulations.
	Personally Identifiable Information - HIPAA	Attach this to the DTUA when sharing data that contain identifiers and the data collection was governed by HIPAA.
	Personally Identifiable Information - FERPA	Attach this to the DTUA when sharing data that contain identifiers and the data collection was governed by FERPA.
	Other	Attach this to the DTUA and insert data protection terms when your data do not fit into any of the above categories or no specific data protection terms are required.

The DTUA templates/samples are not intended for use in transferring materials. The FDP DTUA Guidance Chart provides further guidance on when a DTUA may be needed and/or when data terms may be incorporated into another agreement, such as a Material Transfer Agreement when both data and materials are being shared. Your institution may use other standard template agreements for material transfers, such as the Uniform Biological Material Transfer Agreement (UBMTA). The UBMTA could be incorporated into the DTUA by reference in Attachment 1 or as a separate attachment to the DTUA.

The FDP DTUA templates and samples are not designed for use where third party rights attached to the data are inconsistent with the template terms. See Q6 for more information.

2. Can I use the DTUA to share any kind of information that cannot be made publicly available?

The DTUA template should not be considered appropriate for use in every data transfer and use scenario. For situations involving the transfer of highly controlled or sensitive information, such as classified data, export controlled data (other than data designated as EAR99), or data subject to foreign laws and/or regulations (such as the European Union's General Data Protection Regulations (GDPR)), the DTUA template should not be used.

3. What if I need to share data with an entity not contemplated by the DTUA?

The terms and conditions of the DTUA are designed to cover the risks encountered by non-profit, federal, and educational institutions when they share data under typical research conditions; these terms and conditions are not entirely appropriate for data centers or registries, or when sharing data with a for-profit or foreign entity. However, the FDP recognizes that the language contained within the template can be a useful starting point when creating DTUAs for these other situations. Therefore, you may copy the terms into a customized template, so long as your custom template does not reference the FDP.

4. Could my institution choose to edit the FDP DTUA Templates or Samples so that they may be used for a circumstance not covered by the published documents?

The FDP DTUA Working Group recognizes that the published DTUA One-Way and Reciprocal Templates do not cover all data transfer and use scenarios. In those limited cases not covered by the published DTUA templates, institutions can choose at their own risk to make edits to the FDP DTUA templates and issue their own form of agreement. However, they must remove references to FDP anywhere it appears within the template, and the agreement should look distinct. This is necessary to facilitate review and make clear to the other party that the commonly accepted FDP DTUA language has been changed from the template which has been published on the FDP website. This flexibility does not extend to instances for which the template has been designed.

The Collaborative DTUA and the Public Health Emergency DTUA Samples include sections within them that are editable and allow more latitude for modification to, or addition of, terms and conditions. However, the Public Health Emergency DTUA is meant to provide a way to transfer data easily in order to address the urgent need to transfer data quickly specifically for public health emergency research; therefore, editing and adding other terms and conditions and/or using this sample for non-public health emergency related research are discouraged. As with the standard templates, if any changes to the terms and conditions are made, references to FDP, including the moniker on the face page of the sample, must be removed. We recommend flagging for the other party(ies) the terms which have been changed from the standard sample language.

5. When should a DTUA be used with a funded subaward agreement?

The FDP Subaward Template now provides the parties the opportunity to incorporate terms and conditions that may otherwise be included in a separate DTUA within the subaward to alleviate the need for the parties to execute a separate agreement, with the understanding that many institutions may still require a separate DTUA due to their institutional policies, procedures and/or structure. This section of the Subaward Template is intended to prompt the parties to consider whether a DTUA or incorporation of special language in the subaward is needed at the time that the initial subaward is issued, as this could help alleviate delays in the transfer of human subjects data needed to perform the project. In January 2020, the FDP published Attachment 7 to the FDP Subaward Template, which can be used to incorporate Human Subjects Data Transfer and Use Terms into the subaward agreement, if appropriate.

Use of Attachment 7 to incorporate these terms into the subaward agreement may be useful to:

a. facilitate compliance, ensure appropriate record retention, and enhance the efficiency of the negotiations by having the terms that govern all aspects of the project in one place;
b. ensure there are no conflicting obligations within multiple agreements;
c. provide a broader, more complete context for the data transfer by having the data and Scope of Work in the same agreement;
d. ensure all parties are aware of and agree to the data transfer up front to avoid future project delays; and
e. ensure that the relevant IRB(s) is aware of and has approved, if applicable, the specifics of the exchange prior to execution of the subaward and subsequent authorization of the work to start.

Use of a stand-alone DTUA (whether using an FDP template/sample or another format), rather than Attachment 7, is recommended when:

a. The Recipient needs to use the Data for purposes beyond or outside of the subaward SOW;
b. The Provider is sharing Data that requires protections not included in Attachment 7; and/or
c. There are multiple types of data and multiple parties involved.

When a stand-alone One-Way DTUA is used in conjunction with a subaward agreement, the subaward number can be cross-referenced in Article 1 of the Face Page. See QXXX for more information.

The FDP Subaward Template Attachment 7 PILOT FAQS provide more detailed guidance on use of the FDP Subaward Template Attachment 7.

6. What are some examples of third-party rights that might mean that I can't use the FDP DTUA templates/samples?

Third party rights can attach to a data set in a broad array of circumstances. Examples include:

1) The entity that funded the study under which the data was obtained;
2) The data set was obtained from another party via a different Agreement;
3) Privacy of the persons from whom the data were collected; and
4) The country or jurisdiction in which the data were collected.

For instance, certain data collected in the European Union (EU) are subject to the General Data Protection Regulation (GDPR). The FDP DTUA templates/samples are not appropriate for data subject to the GDPR. The templates/samples likewise would not be appropriate for data collected in the course of research deemed to be export controlled or when a for-profit funding agency had applied special terms regarding commercialization restrictions. Consent form language may also pose additional concerns for sharing with third-parties: for instance, the IRB may need to review the original consent form to determine whether it allows for the data to be shared with the intended Recipient. Finally, data is often collected across multiple entities, such as when an academic institution collects data from affiliated hospitals, and agreements between these entities may inform how and/or with whom the data may be shared.

Any underlying agreements regarding the arrangement should be reviewed to ensure there is no disagreement with the terms of the template/sample. If any underlying agreements require the addition or flow-down of terms, then use of the FDP DTUA template/sample is not appropriate. The FDP does not recommend using the templates/samples to share data that any of the above-referenced agreements would not permit to be shared for the proposed DTUA purpose.

7. Do I always need to include something as Attachment 2?

Yes; some version of Attachment 2 must always be included to draft a complete DTUA, even if no special terms and conditions apply. In the event there are no special terms and conditions to include, use the Attachment 2 – Other and select the check box next to the text, "None. No additional terms and conditions are required."

8. What is the intended use of Attachment 3?

Attachment 3 of the One-Way Template was created to allow the Provider the option to authorize Collaborator Personnel (individuals who are employed by another organization and are not under direct control of the Recipient, and who, by nature of their participation in the Project, need to have access to the Data) to access the data via the Recipient. These individuals might include, for example, those affiliated with another entity that also has a DTUA with your organization for this project (multi-site project), a visiting professor working at the Recipient while on

sabbatical, or individuals at an institution that might receive only a portion of the Data from the Recipient under conditions that would not require a separate DTUA.

There is also an Attachment 3 in the Reciprocal Template and the Collaborative Sample. Attachment 3 in these documents allows the parties to identify additional individuals with a need to access the Data for the conduct of the Project. Such individuals are employed by another organization and are not under direct control of one of the parties to the agreement. Compared to the One-Way Template, there is slightly different terminology to reference these individuals in both the Reciprocal Template and the Collaborative Sample where they are referred to as 'Third Party Personnel' instead of 'Collaborator Personnel'.

Attachment 3 is not to be used to list authorized data users from the Recipient (One-Way Template) or Receiving Party (Reciprocal Template or Collaborative Sample). See Question 14 for more information on how Recipient/Receiving Party Personnel are already covered in the DTUA.

9. Our legal counsel would like to make changes to the terms and conditions of the FDP DTUA templates. May we do this?

The terms and conditions of the FDP DTUA templates should not be modified except in the case of the editable parameters built into the templates (i.e., the form fields in Attachment 1) when issuing DTUAs to another domestic nonprofit entity. The FDP DTUA templates are collaborative documents developed by an FDP working group that included broad representation of the membership. They were distributed for review and vetting by the full membership prior to publication. This collaboration has resulted in templates that reflect a widely accepted set of standard terms and conditions for the most commonly shared data types. The overarching goal of the DTUA project, reducing the administrative burden associated with sharing data that cannot be made publicly available, cannot be realized if member institutions alter the terms and conditions of the templates.

If using a DTUA template for a circumstance that the template is not intended to cover, such as sharing data with a foreign recipient, you may modify the standard template language for such a case; however, please remove the FDP moniker so that it is clear the FDP standard template language was altered.

The FDP DTUA samples are intended to provide greater flexibility to the parties in incorporating edits necessary to accommodate project-specific requirements. If the sample can be used without modification to the terms, then it is appropriate to retain the FDP moniker to signal this to the other party(ies). As with the standard templates, if any material changes to the terms and conditions are made, references to FDP, including the moniker on the face page of the sample, must be removed. We also recommend flagging for the other party(ies) the terms which have been changed from the standard sample language.

9. Why isn't an indemnification provision included in the templates/samples?

An indemnification should not be needed to cover liability which could be generated by the data recipient. The liability language utilized in the templates/samples is modeled off that used in other standardized templates, such as the Uniform Biological Material Transfer Agreement. The

recipient of the data agrees to accept liability for its use, storage, disclosure, or disposal of the data, except to the extent such liability is caused by the negligence or willful misconduct of the provider of the data, and the provider of the data provides an assurance that they have the right to provide the data for use in the project. In the event that the data recipient engages in unauthorized or inappropriate use of the data, the provider of the data would be able to make a direct contractual claim based on the recipient's obligations outlined in the DTUA. Additionally, many organizations, such as federal agencies or state institutions, are not able to provide an indemnification.

11. Where can I add my special terms and conditions?

The DTUA Templates/Samples were created to encourage consistency among Data Providers and Recipients and reduce the administrative burden and delay caused by the use of special terms and conditions that may not be necessary or applicable to agreements between FDP members. That being said, the DTUA Templates/Samples do allow for certain categories of terms and conditions to be incorporated, if such language is required due to the nature of the Data and Project. Changes to the language in the DTUA Templates/Samples other than as outlined below for each Agreement type would require removal of the FDP moniker.

- For the One-Way Template: Attachment 1 allows for the inclusion of project-specific terms. Paragraph 3 provides for inclusion of any requirements pertaining to the transfer of the Data, such as instructions for transmitting or accessing the Data. Article 1 on the Face Page allows for documentation of any fees or funded agreements applicable to the data exchange. .Paragraph 4 provides for inclusion of any disposition requirements that may apply to the Recipient upon termination or expiration of the Agreement, such as a date by which the Data must be returned or destroyed, a method of destruction, or any required documentation of the Data's disposal.

- For the Reciprocal Template: Attachment 1 allows for the inclusion of project-specific terms. Paragraph 3 provides for the addition of Party 1's disposition requirements upon the termination or expiration of the Agreement, and paragraph 6 provides for the addition of Party 2's disposition requirements upon the termination or expiration of the Agreement.

- For the Collaborative Sample: The Signature page of this sample allows for inclusion of Disposition Instructions where any specific disposition instructions for the Data at expiration or termination of the Project are to be added. The Signature page also includes an "Other Special Instructions" section, which provides for any additional instructions for Data transfer and use but not the description of the Data. This section should not be used to impose additional requirements inconsistent with the other terms of this Agreement. Examples of information recommended to be provided include, if/how Data will be revised and resent if errors are found by the Receiving Party, specific instructions necessary to complete the transfer of the Data, if available/appropriate, and any support supplied by the Providing Party for the transfer. Additionally, the Collaborative Sample provides suggestions for section 5, Publications, and section 8, Termination. If the sample language in these sections does not fit the needs of the Project, they should be modified accordingly, and the FDP moniker removed.

- For the Public Health Emergency Sample: Attachment 1 includes editable sections, but these are specified for the description of the data and the description of the project. The sample's purpose is for use with two parties when only one is providing de-identified data or a Limited Data Set related to a public health emergency. This sample allows for specific options to be checked to allow limited flexibility in some of the sections. Because of the urgent need for the transfer of Data for public health emergency research, adding additional special terms and conditions is discouraged as counterproductive.

12. My institution wants to add specific information security requirements. Where can I add those?

The purpose of the DTUA template is to minimize the addition of institution-specific terms, conditions, and controls. The template has been carefully developed for use in many of the most common data transfer and use transactions encountered. As such, the template includes references to those laws and regulations of the United States which are commonly applicable to the transfer and use of data and contains reasonable and acceptable requirements in Attachment 2 for the protection of the types of data for which use of the template is deemed appropriate.

However, the template should not be considered appropriate for use in every data transfer and use scenario. For situations involving the transfer of highly controlled or sensitive information, such as classified data, export controlled data (other than data designated as EAR99), or data subject to foreign laws and/or regulations (such as the European Union's General Data Protection Regulations (GDPR)), the DTUA template should not be used. For those situations involving data for which the use of the template is appropriate, the inclusion of additional terms and conditions generally adds additional administrative burden without enhancing the protections for the Data or Provider.

If a Provider believes the Recipient to be at high-risk for data loss or inappropriate data exposure, or that the Recipient will otherwise be unable to adhere to the applicable laws and regulations, either the Data should not be shared or the template should not be used for that specific data transfer. In such circumstances, the development of a project-specific DTUA, which includes additional specific controls, requirements, or remedies in the event of data loss or inappropriate data exposure, would be more appropriate.

13. The template doesn't include any references to cloud storage. Does this mean that the Recipient is permitted to store the Data in the cloud? Or is this prohibited since it isn't mentioned?

The DTUA template is designed to be a living document that can accommodate rapidly changing technology and therefore is intentionally silent regarding the type of storage used to house the data once transferred. Instead, we have focused the template language on the protections required for housing that data under applicable laws and regulations, irrespective of the type of storage used (e.g., cloud server vs. local server).

14. My institution would like to require a list of individuals who will access the data on behalf of the Recipient. Where in the Agreement should this be incorporated? May I require that a formal amendment must be processed each time there are changes to this list?

Please do not use Attachment 3 to provide or request such a list. The face page carefully defines authorized persons as, “Recipient Scientist and Recipient’s faculty, employees, fellows, students, and agents ("Recipient Personnel") and Third Party/Collaborator Personnel (as defined in Attachment 3) that have a need to use the Data in connection with the Project, provide a service with respect to the Data and whose obligations of use are consistent with the terms of this Agreement (collectively, "Authorized Persons").” Therefore, there should not be any need for the Provider to contractually permit each individual user by name to access the data. If the Provider requires the information of the individuals who have access to the data, the most feasible way to accomplish this is to require that the Recipient provide a report of the individuals with access to the Data. This reporting requirement, instructions for individual users to access the data via VPN, or other special instructions on qualifications of individuals who access the data may be appropriately incorporated into the One-Way DTUA in Section 3 of Attachment 1, the Signature Page of the Collaborative DTUA Sample, or the definition of Third Party/Collaborator Personnel in Attachment 3. To avoid executing unnecessary amendments to change personnel lists each time, do not include the personnel list in the agreement. Please note that the Recipient individual users of the Data are tracked by IRB protocol and approvals, if subject to IRB review. As such, the list of Recipient personnel accessing the Data will also be tracked the same way.

Note: This is not applicable to Recipient Scientist changes or any other change(s) requiring an action to be taken with the Agreement.

15. How can I use the Amendment template to change both PIs or the type of DTUA signed?

Not all DTUA changes are appropriate to be handled via simple amendment. If the nature of the data exchange is altered so that the data flow is different than in the original agreement, the original agreement should be terminated and replaced with a new DTUA. Changing both PIs in a two party DTUA may be a significant change that warrants execution of a new DTUA, but may vary based on institutional business practices.

16. Does the Sample For Scientists Transferring Institutions serve as a novation agreement for transfer of third-party data?

The FDP does not recommend novation agreements for transfer of third-party data when a PI moves between institutions. We recommend that the original DTUA be terminated and a new DTUA negotiated between the PI’s new institution and original data provider. None of the FDP DTUA templates and samples have terms that are consistent with the flow-through of terms from other agreements.

17. Why doesn’t the Sample For Scientists Transferring Institutions assign ownership of the Data to the Recipient institution?

In keeping with all other FDP initiatives, this sample was designed to be universally accepted. Institutions vary significantly in their policies around assigning ownership of their data, and this may vary within an institution depending on the nature of the data. Thus,

this sample is intentionally silent on this issue. However, institutions are welcome to modify this sample to fit their policies as long as the FDP branding is removed.

18. Only one party is providing Data, but the two parties contemplate using the Data to collaborate on publications. Which template should I use?

Even when only one party will be providing Data, the Reciprocal DTUA Template can be used if the parties want to be sure that the Agreement language addresses how collaborative publications arising from the project will be handled. In such a case, we recommend designating the party providing the data as Party 1, and the party who will be only receiving data as Party 2. On Attachment 1, then simply indicate "None" in the "Description of Party 2 Data" text box and "Not Applicable" in the "Party 2 Disposition Requirements upon the termination or expiration of the Agreement" text box.

If the parties are not concerned about reflecting the potential for collaborative publications in the agreement, then the One-Way DTUA Template could be used instead.

19. Information about the Parties is not included in the header of the Collaborative Sample. Where should I include the information specific to each Party?

The Collaborative Sample is a multi-party Data Transfer and Use Agreement that can incorporate any number of parties. Since the intent of this Agreement is to allow for more than a bidirectional data transfer, it would be difficult to anticipate the space needed to provide the information for all parties on the face page. Each Party's specific information will be incorporated in its respective signature page to allow for as many parties as needed.

The Signature Page will identify if the Party involved is a Providing Party, Receiving Party, or both under the Agreement. The Signature Page is where the Providing Party's Data-specific information will be incorporated: description of Data, disposition requirements, and other special instructions. Please pay particular attention to the "Instructions to the drafter" on the signature page. Additional terms and conditions should not be included in this section. Please see FAQ Question 11 "Where can I add my special terms and conditions" for more information.

20. What factors should the parties consider in crafting the termination clause in the Collaborative Sample to meet the needs of the project?

Determining appropriate termination language for a Collaborative DTUA is highly context-dependent and the parties will want to consider many factors before finalizing this section of the agreement:

- Sensitivity of the Data: The more sensitive the data shared, the more likely that Providing Parties will require destruction or return of their

data if they choose to terminate their participation in the contract. Conversely, if the data are thoroughly de-identified, Providing Parties might have greater flexibility to permit continued use of the data after they leave the project.

- Impact of loss on a single party's data to the project: If the project is large with many parties, it is likely that termination by a single party (along with the loss of their data) will have a small impact on the overall project. On the other hand, if a party leaves a small project, or if the terminating party is critical to the overall success of the project, you might need to terminate the contract for all parties if one leaves. If the DTUA relates to an externally funded project, the data sharing requirements of the funded agreement(s) must be considered when drafting this section of the agreement.
- Whether a single party's data can be extracted from the compiled database.
- Impact to the project if a single party breaches their obligations with respect to the Data: In the case of termination for cause or breach, it could be possible that the breaching party's actions are serious enough to call into question the entire database, and the entire agreement should be terminated and all data returned to the respective Providers. For less serious breaches, the breaching party should be given appropriate notice, and if the breach isn't cured in the allotted time, the participation of just that party should be terminated.
- Obligations of one or more of the Parties to an external funder: If one or more of the Parties needs the Data to be able to meet deliverables or other obligations to an external funder, they may be unable to risk loss of access to the Data because one or more of the other Parties wishes to terminate.

21. In the One-Way DTUA Template, Article 1 of the Face Page of Attachment 1 provides the option for the Provider to request reimbursement for any costs associated with the assembly, preparation, compilation, and transfer of the Data to the Recipient. What are some examples of costs that a Provider could include under this section?

In the One-Way DTUA scenario, if assembly of the Data requires incidental costs that need to be reimbursed, the Provider may request reimbursement. The DTUA templates/samples should not be used for revenue-generating sale or licensing of data, nor should they be used as a substitute for an agreement to support research effort by Recipient staff. The intention of this section is to facilitate reimbursement to the Provider for its actual costs incurred in sharing the Data with the Recipient. Examples of appropriate and inappropriate fees in a DTUA are:

Appropriate fees in DTUAs	Inappropriate fees in DTUAs
Provider's expenses for extracting Data from larger data set, cleaning of Data, etc.	Payments to individuals who are the subject of the Data
Shipment fees related to physical media	Salary support for any Recipient personnel.
Electronic file transfer costs	IRB fees
	Payments for data collection by Data Provider

If the DTUA is executed as required in a subaward or other funded agreement between the parties, that information should be noted in the second checkbox in Article 1 in the DTUA.

The Reciprocal DTUA Template and Collaborative DTUA Sample do not include cost reimbursement language since these agreements involve bi-directional data transfers and/or collaborative projects for which each party will likely assume its own costs for data assembly, preparation, compilation, and transfer. The Public Health Emergency Sample does not include the option for cost reimbursement to avoid added language that may slow down urgent transfers associated with research during a declared public health emergency. The sample for PIs Transferring Institutions states that the data will be transferred at no cost, however, each transaction with this sample should be analyzed to determine if the provision should be altered.

Guidance on Selecting Versions of Attachment 2

22. When would it be appropriate to create a customized Attachment 2?

If a published version of Attachment 2 exists for the type of data being shared, using the published Attachment 2 will help reduce the administrative burden on both parties to the DTUA. However, in the event that you are sharing a unique data set that requires protections other than those found in the existing versions of Attachment 2, you may use "Attachment 2 - Other" to incorporate the required protections for your data set. Please keep in mind that this is not intended to be used to incorporate terms and conditions in excess of or in conflict with what has been agreed to by the FDP membership.

See the below FAQs in this section for further information on selecting the appropriate version of Attachment 2 in various data sharing scenarios.

An example of when Attachment 2 - Other might be appropriate: Your university is based in California. You have a faculty member in the computer science division doing research in collaboration with a law professor at another California university. Your faculty member is collecting data on the efficacy of the Student Online Personal Information Protection Act (SOPIPA), which requires websites to remove student information upon request by the school district. The data being gathered for the collaboration does not include identifiable information on the students but focuses on the school districts. While you are pretty sure that the SOPIPA provisions do not apply to the research, your office would like to ensure that the SOPIPA provisions are flowed down, for the avoidance of any doubt.

An example of when use of Attachment 2 - Other would not be appropriate is when human subjects data has been obtained from a State or Federal Agency, such as the Veterans Health Administration, and you would need to flow-through a publication term or indemnification which would conflict with the same terms included in the DTUA. In such a case, you may choose to use the FDP DTUA template as a starting point and modify to include the flow-through terms as long as the FDP moniker is removed.

23. Is the Provider or Recipient ultimately responsible for determining which version of Attachment 2 is used in the DTUA?

It is the purview of the Provider to determine what type of Data will be shared and, correspondingly, what requirements must be incorporated into the DTUA and which version of Attachment 2 is appropriate. The intent of the DTUA is for the Provider to ensure their obligations are met and not necessarily to cover all obligations that would apply to the Recipient (for example, state laws that would apply to the Recipient but not the Provider may not be incorporated into the DTUA but would still apply to the Recipient).

This determination is different from the process that would be followed in a subaward agreement. In a subaward, the required flow-down terms may depend upon specific characteristics of the subrecipient. Under a DTUA, the Provider owns the data and expects the Recipient to protect the data as necessary for the Provider to make sure that the Provider is able to meet its obligations under law/regulation. The Recipient's obligation is to review the DTUA to ensure that they can meet the stated data protection obligations. In this sense, a DTUA is a simpler transaction and does not need to take into account the entity type of the Recipient.

24. When should one of the versions of Attachment 2 that incorporates HIPAA be used?

If the Data are being disclosed from the Provider's Covered Entity Component or if the Provider is a Covered Entity and the data have not been de-identified to the HIPAA standard, then the Data are governed by HIPAA and the PII-HIPAA or Limited Data Set attachments should be used. Next look to the list of HIPAA identifiers to determine if the Data are fully identifiable or a Limited Data Set (further information available in the FDP Tool for Classifying Human Subjects Data) and pick the appropriate Attachment 2 based on that analysis.

If the Provider is not a Covered Entity or Covered Entity Component, then HIPAA does not apply, and the Attachment 2 for a Limited Data Set or PII - HIPAA should not be used. There is no equivalent to a Limited Data Set under the Common Rule; the Data are either identifiable or de-identified. Please consult your institution's privacy officer to learn how your institution implements these rules.

The Attachment 2 for de-identified data can be used for data generated under either HIPAA or the Common Rule, so long as no identifiers are shared.

25. When would a non-covered entity/component disclose a HIPAA Limited Data Set?

It would not. "Limited Data Set," as used in these Attachments, is a HIPAA term that is only applicable to a HIPAA Covered Entity. The Attachment 2 for a Limited Data Set assumes that the Provider is a HIPAA Covered Entity (see Number 4 in that Attachment). The Covered Entity/Component status of the Recipient does not impact this selection by the Covered Entity Provider.

26. My institution is not a covered entity. Can my institution receive Protected Health Information (PHI) (including a Limited Data Set) from a Covered Entity?

Yes; a HIPAA Covered Entity may disclose patient PHI for research pursuant to either an individual's Authorization, an IRB or Privacy Board Waiver of Authorization, or as a Limited Data Set. Covered Entities may also provide data that has been de-identified in accordance with HIPAA, in which case it is no longer PHI under HIPAA (and would also no longer be considered identifiable under the Common Rule).

27. Which attachment would an entity that is considered a Hybrid under HIPAA use?

See the FDP DTUA Project Glossary for more information on the definitions of Hybrid and Covered Entity. Hybrid entities under HIPAA contain both HIPAA-Covered Components and non-covered components. The Hybrid's Covered Components are subject to HIPAA in the same way as a HIPAA Covered Entity and should use the version a Covered Entity would choose in the same circumstances. The Hybrid's non-covered components are not subject to HIPAA and would make the same choice as an entity that is not subject to HIPAA in the same circumstances.

28. As the Provider, what information do I need to gather and consider in order to make a determination on which version of Attachment 2 I should use?

Step 1: Determine what type of entity you are sending the data from. See the FDP DTUA Project Glossary for definitions of the different entity types for assistance in making this determination

Step 2: Classify the data you are sharing. See the FDP Tool for Classifying Human Subjects Data for guidance on how you can distinguish between the different categories of data.

Step 3: Confirm that you have the authority to share the data for the purpose being described in the DTUA under the laws/regulations that apply to you

Example 1: I am a Non-Covered Entity/Component under HIPAA, and I will provide a dataset containing date of birth (MM/DD/YYYY) to a Covered Entity/Component.

Resolution 1: Because the Provider is not part of a Covered Entity/Component, neither the Limited Data Set nor HIPAA Attachment 2s would be appropriate. Many institutions would consider this identifiable data under the Common Rule, but check with your privacy officer to confirm your institution's practice. Once the Data are accepted, the Recipient can apply whatever additional protections beyond the DTUA that they deem appropriate.

Example 2: I am a Covered Entity/Component under HIPAA, and I will share a Limited Data Set with a Non-Covered Entity/Component.
Resolution 2: The Limited Data Set Attachment 2 is appropriate.

29. How does the HIPAA status of the Provider and Recipient affect the choice of Attachment 2?

There will be some situations where the determination is more complex, but the FDP DTUA Provider Guidance Chart is a good guide. Organizations should also remember to check with their legal counsel regarding the guidance provided in the chart as different institutions may classify these data and their status differently.

30. Which version of Attachment 2 should I choose if the data I am sending could be considered both PHI and Education Records?

The Department of Health and Human Services (DHHS) has published a helpful guidance on the difference between educational records and treatment records under FERPA, available here: https://www.hhs.gov/hipaa/for-professionals/faq/518/does-ferpa-or-hipaa-apply-to-records-on-students-at-health-clinics/index.html. If a single data set includes both educational and health records, please also see Question 20 for the DTUA Working Group's recommendation on how to handle these complex/combined data sets. You may also want to engage your institution's privacy officer to determine the best way to handle these complex determinations consistent with your institution's policies and procedures.

31. Are there instances in which a DTUA could include multiple Attachments 2s?

How this is handled will depend on the study design, and which contract template or sample is most appropriate for the data exchange. For the One-Way template, we would expect only one Attachment 2, determined by the Provider. For the Reciprocal template, if each party is contributing a different type of data, the DTUA would include 2 different Attachment 2s; however, there is no need to attach multiple Attachment 2s if both parties are sharing the same data type. In the Collaborative sample, each party includes an Attachment 2 with their signature page, so the number of Attachment 2s would equal the number of parties to the contract. Should a party to a Reciprocal or Collaborative DTUA not contribute data, the Attachment 2 type should be "Other", and the word "None" inserted into the blank field.

The possibility of multiple Attachment 2s raises the issue of determining the most appropriate data protections for the project database. Any time multiple types of data are combined into a single database, the entire database must be used and secured in accordance with the most restrictive regulations/requirements applicable to any of the data types included.

When shared data sets will be maintained separately, we recommend issuing separate agreements so that all parties are clear which restrictions apply to which data sets.

Guidance for Transferring Personally Identifiable Information

32. What is Personally Identifiable Information (PII)?

Please refer to the FDP DTUA Project Glossary for definitions. PII is a broad term that encompasses PHI, as well as other personally identifiable information. While PII is not a defined term under the Common Rule, the Common Rule includes the term "...individually identifiable information..." in its definition of human subject research and does incorporate the concept of PII.

33. Why are there three versions of Attachment 2 for PII?

The original intent of the DTUA Template Working Group was to create a single Attachment 2 to the DTUA to cover PII. However, based on the collective experiences of the Working Group members, which included representatives from both public and private institutions as well as government agencies, we determined that the most effective course would be to create three versions tailored to the specific regulations governing the data. Working Group members have found that incorporating references to regulations that don't apply to the particular data being shared could be inappropriate, concerning, and confusing.

34. What categories of PII are covered by the DTUA template components?

There are three versions of Attachment 2 that work for PII; they include:

- PII - FERPA: The Family Educational Rights and Privacy Act (FERPA) (20 U.S.C. § 1232g; 34 CFR Part 99) is a Federal law that protects the privacy of student education records. The law applies to all schools that receive funds under an applicable program of the U.S. Department of Education. More information on FERPA privacy regulations may be found at https://www2.ed.gov/policy/gen/guid/fpco/ferpa/index.html

- PII - HIPAA: The regulations implementing the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (45 CFR Part 160 and Part 164) includes mandated standards for the secure electronic storage and transmission of healthcare information. To comply with these standards, the Department of Health and Human Services issued two regulations, administered and enforced by the Office for Civil Rights: the Privacy Rule and Security Rule. More information on HIPAA privacy regulations may be found at https://www.hhs.gov/hipaa/index.html. HIPAA applies only to Protected Health Information, which is information about the health of an individual created or received by a HIPAA Covered Entity, and which has not been de-identified in accordance with HIPAA's requirements. Please note that a separate version of Attachment 2 has been developed for use in sharing Limited Data Sets; therefore, this version of Attachment 2 should only be used when the data set includes more identifiers than would qualify it as a Limited Data Set.

- PII - Common Rule Only: The Common Rule Only version of Attachment 2 should only be used when neither FERPA nor HIPAA apply to the identifiable data being shared. The Federal Policy for the Protection of Human Subjects or the "Common Rule" was published in 1991 and codified in separate regulations by 15 Federal departments and agencies:
    1. Department of Agriculture: 7 CFR Part 1c
    2. Department of Energy: 10 CFR Part 745
    3. National Aeronautics and Space Administration: 14 CFR Part 1230
    4. Department of Commerce - National Institute of Standards and Technology: 15 CFR Part 27
    5. Consumer Product Safety Commission: 16 CFR Part 1028
    6. Agency for International Development (USAID): 22 CFR Part 225
    7. Department of Housing and Urban Development: 24 CFR Part 60
    8. Department of Justice - National Institute of Justice: 28 CFR Part 46
    9. Department of Defense: 32 CFR Part 219
    10. Department of Education: 34 CFR Part 97
    11. Department of Veterans Affairs - Office of Research Oversight - Office of Research and Development: 38 CFR Part 16
    12. Environmental Protection Agency - Research and Development: 40 CFR Part 26
    13. Department of Health and Human Services: 45 CFR Part 46
    14. National Science Foundation: 45 CFR Part 690
    15. Department of Transportation: 49 CFR Part 11

  The Central Intelligence Agency, the Department of Homeland Security, and the Social Security Administration also comply with all subparts of 45 CFR part 46.

  More information on Common Rule privacy regulations may be found at https://www.hhs.gov/ohrp/regulations-and-policy/regulations/finalized-revisions-common-rule/index.html. The revised Common Rule went into effect January 21, 2019. We do not currently anticipate that the revisions to the Common Rule will impact the requirements included in the DTUA, but institutions using the DTUA are responsible for ensuring that their use of the template remains consistent with applicable laws and regulations as they may be updated or revised.