

## **FDP Subaward Template Attachment 7 PILOT FAQs**

**Introduction:** The [FDP Human Subjects Data Transfer and Use Terms \(HSDTUT\) Attachment 7](#) is in a pilot phase. These FAQs are specifically written to provide guidance on the use of Attachment 7 for the FDP [subaward templates](#).

FDP pilots are experimental. They are designed to test new processes to determine if a change would add value by reducing administrative burden. While some institutions may be ready to pilot certain initiatives immediately, others, due to the size and/or organizational structure and needs of their institution, may need to take a slower approach to change. Accordingly, the FDP expects that there will be institutions that are not ready to pilot Attachment 7 at this time or there may be scenarios in which the addition of Attachment 7 may not be the best choice to exchange a particular data set, as described below.

The spirit of the FDP is one where institutions collaborate to find the best methodologies to reduce burden, a large part of which includes flexibility on the part of both the early adopters and those institutions that continue utilizing the already available methods.

As such, we ask both piloting institutions and those not able to pilot Attachment 7 to be flexible with each other during the pilot phase of Attachment 7. There may be institutions unable to accept the inclusion of HSDTUT terms into their subawards, while others begin to formulate new processes built around incorporating data use terms into their subawards and reducing the number of stand-alone DTUAs. Please be open to the perspectives and business requirements of your colleagues and uphold the core commitment of FDP: to communicate and collaborate to reduce burden.

Thank you!

1. I'm not familiar with the language needed to transfer/share human subjects data. What is it and when is it needed to cover the transfer of human subjects data?
  - a. HSDTUT language defines the type of human subjects data exchanged, any applicable legal requirements attached to the data, and how exchanged data may be accessed and/or used. Such terms may be stated in a standalone Data Transfer and Use Agreement (DTUA) or be embedded into or attached to a subaward (i.e. Attachment 7) or other collaboration agreement. The [FDP DTUA Guidance Chart](#) provides guidance on determining when a DTUA or Attachment 7 may be required to transfer human subjects data. For purposes of completing the FDP subaward template, Attachment 7 may be used to govern transfer and use of data related to a pre-existing data set or data created or gathered in the performance of the subaward.
  
2. Why is it useful to include HSDTUT language in the subaward?

Some institutions include HSDTUT within the subaward 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, complete context for the data transfer by having the data and Scope of Work in the same agreement; and
  - 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.
3. What are the differences between the Attachment 7 language and the DTUA terms? Please see the crosswalk detailing these differences and the accompanying rationales. An overview of the key differences includes:
- a. The DTUA includes liability language modeled off that used in other standardized templates, such as the Universal Biological Material Transfer Agreement. Attachment 7 does not include liability language beyond the standard language included in the subaward template. Given the collaborative nature inherent in a subaward project, the liability language in the subaward should be sufficient. In the event that the data recipient engages in unauthorized or inappropriate use of the data, the provider would be able to make a direct contractual claim based on the recipient's obligations outlined in Attachment 7. Therefore, an indemnification should not be needed to cover such liability which could be generated by the recipient. If, however, your institution is required by counsel or formal policy to include an allocation of liability for a data transfer, the below language may be used, but please note that no indemnification is intended by either party under the below:

*Except to the extent prohibited by law, the Recipient assumes all liability for damages which may arise from its use, storage, disclosure, or disposal of the Data. The Provider will not be liable to the Recipient for any loss, claim, or demand made by the Recipient, or made against the Recipient by any other party, solely due to or directly arising from the use of the Data by the Recipient.*
  - b. Publication language is included in the DTUA but is not typically included in the FDP Subaward template. Following the FDP Subaward convention, publication language is not included in Attachment 7. The Parties should rely on the usual and customary collaboration on publications that is inherent in subaward activities.
  - c. Attachment 7 does not include language regarding ownership of the data. Rights in Data generated in the course of the subaward are covered in Attachment 2. The federal awarding agency terms govern rights in data generated in the course of the project. Attachment 7 then lays out specific terms and conditions needed

to protect the human subjects data and does not transfer or convey additional rights in the data.

4. How do I use Attachment 7?

Attachment 7 provides standard language for FDP institutions to utilize when incorporating HSDTUT into the FDP subaward templates. It allows PTEs to choose an option of having HSDTUT be part of the FDP subaward template, instead of issuing a subaward and then setting forth the terms of exchanging Human Subjects Data in a separate DTUA. Both the subaward template and DTUA template include terms such as liability, use of name, and termination, so using Attachment 7 may eliminate conflicting terms and ensure clarity and consistency. Attachment 7, then, serves to describe the data to be transferred, the flow of the data, and the terms and conditions specific to the type of data being transferred.

Inclusion of data transfer and use terms in the subaward remains optional; however, if the parties agree to include it, the following steps apply to the FDP subaward template:

- a. In Attachment 2, “Federal Award Terms and Conditions,”:
  - i. Under Human Subjects Data, select “Applicable” from the dropdown.
  - ii. Under the next drop down, “The PTE will set forth the terms of the exchange of Human Subjects Data (Select One):”, select “ in Attachment 7.”
  - iii. Under “Human Subjects Data” will be exchanged under this Subaward (check all that apply):” select either or both “From Subrecipient to PTE”, “From PTE to Subrecipient”, to reflect the flow of the data.
- b. In Attachment 7, “Human Subjects Data Transfer and Use Terms,”:
  - i. Under “Human Subjects Data” will be exchanged under this Subaward (check all that apply): select either or both “From Subrecipient to PTE”, “From PTE to Subrecipient”, to reflect the flow of the data.
  - ii. Under “The Data to be shared will be” select the data type (see question 5 for more details). Language applicable to that data type will auto-populate into page 2.
  - iii. Enter a Description of Data in the text box The Provider may reference the Protocol in its description of the data, including via incorporating the protocol by reference. The Provider may also reference the Statement of Work (Attachment 5).

5. How do I determine which type of data is being shared?

The [FDP Tool for Classifying Human Subjects Data](#) can be used to help determine which type of data is being shared.

- a. **De-identified Data**<sup>1</sup>: Data that does not include any Personally Identifiable Information (PII) or Protected Health Information (PHI) elements included in the HIPAA 18

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<sup>1</sup> When you send data from a covered entity to a non-covered entity, the data is no longer covered by HIPAA. More information on this is contained in the [FDP DTUA FAQ's](#).

identifiers list which may be used alone or with other sources to identify an individual. When data is de-identified within the meaning of HIPAA, data is stripped of all possible identifiable information. There can be none of the 18 PHI elements present in the data set.

- b. **Limited Data Set:** A Limited Data Set contains only specific PHI elements that HIPAA allows to be present in a Limited Data Set. The data elements included are generally broad enough so that tracing any back to one specific individual would be difficult (but likely not impossible). HIPAA requires very specific language for Limited Data Set data transfers. See [FDP Tool for Classifying Human Subjects Data](#) for a guide to determine when Limited Data Sets are being used.
  - c. **Protected Health Information (PHI):** A PHI dataset includes more PHI elements than what HIPAA allows in a Limited Data Set. By law, PHI (more than a Limited Data Set) cannot be shared unless the provider has obtained IRB approval or a Waiver of Authorization and the study subject has consented to share their data for the purpose outlined by the subaward or DTUA.
  - d. **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.
6. When shouldn't I use Attachment 7?
- a. If the Recipient needs to use the Data for purposes beyond or outside of the subaward SOW, then a stand-alone DTUA should be used.
  - b. If the Provider is sharing Data that requires high levels of protection, then utilize a stand-alone DTUA, or another separate agreement that allows the Provider to include the additional terms necessary.
  - c. If there are multiple types of data and multiple parties involved, then a separate DTUA or another separate agreement would be more appropriate to outline the multiple phases/types/parties.
7. What about European data (aka General Data Protection Regulations “GDPR”)? Can I use Attachment 7 to share any kind of controlled information?

Just say no! Attachment 7 is not designed to cover the requirements of GDPR or controlled information.

Attachment 7 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), a separate DTUA, and not Attachment 7, should be used.

8. What if the other party doesn't believe HSDTUT are necessary or wants to include HSDTUT that I don't think are necessary?

- a. **Incorporating text:** Many organizations are required by law or policy to document any outgoing transfer of human subjects data and have built robust business processes to ensure the execution of these obligations.

If the PTE knows there will be a data transfer to or from the subrecipient under the subaward, and their business processes allow for the inclusion of Attachment 7, they may choose to include the appropriate data language via Attachment 7.

If the subrecipient disagrees with using Attachment 7, they should discuss with the PTE. As a reminder, this is a pilot and organizations using Attachment 7 may need to accommodate institutions that are not yet able to use Attachment 7.

- b. **Resolving conflicts around data type:** To reduce administrative burden, the Data Recipient should limit any negotiation to the kinds of data they will be receiving, particularly if the data type (de-identified, Limited Data Set, PHI), is unexpected or does not match the Recipient's original expectations. The parties should not negotiate the language of Attachment 7 without a clear and compelling reason. In most cases, Attachment 7 language should sufficiently cover either party's data transfer.

In rare cases, a separate DTUA may be appropriate if the Provider decides that the data set requires additional protections, represents a very large amount of data, or has other unique characteristics (see question 6).

It is the purview of the Provider to determine what type of Data will be shared and, correspondingly, which version of Attachment 7 is appropriate.

Under Attachment 7, the Provider is ultimately responsible for 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 terms of Attachment 7 to ensure that they can meet the stated data protection obligations and to raise any questions they may have about the type of data being provided, as discussed above.

*However, a Provider cannot be expected to provide any human subjects data unless and until the transfer is protected by data terms, either in a separate DTUA or through Attachment 7.*

9. Can I use this language to share human samples/materials in addition to data?

No, this language has been designed specifically to cover only the transfer and use of human subjects data.

10. What if the nature of any data sharing isn't known at the time the parties are ready to execute the subaward?

If you can determine that there is some data being shared but the specifics can't be determined, either a separate DTUA can be done later or you can amend the subaward to incorporate Attachment 7.

- a. If adding Attachment 7 at a later point in time, perhaps indicate in Attachment 2 if you plan to amend the sub to add Attachment 7 later so that both parties agree in advance to the addition of Attachment 7, when it becomes applicable.
- b. If you will be issuing a separate DTUA, use the "Via a separate Data Use Agreement" option in Attachment 2. If this option is selected, an amendment to the subaward will not be necessary.

11. What do I do if both parties are sharing Data, but each party is sharing a different type of data (e.g. PTE is sending the subrecipient a Limited Data Set and the subrecipient is sending the PTE a de-identified data set)?

- a. The parties have the option to attach two separate Attachment 7 forms to the subaward; one Attachment 7 for the data type to be shared from PTE to Subrecipient and a second for the data type to be shared from subrecipient to PTE.
- b. If the parties are sharing different types of data sets with one another, but plan to combine the Data into one data set, then the parties may attach one Attachment 7 form to the subaward, choosing the most restrictive data type language. Using the scenario above: the PTE is sending the subrecipient a Limited Data Set (LDS) and the subrecipient is sending the PTE de-identified data to be combined into one data set, attach an Attachment 7 form to the subaward, check off both boxes indicating the direction of the data transfer, and select the LDS option.
- c. Use a separate, stand-alone DTUA.