Attachment 7 is designed to incorporate DTUA (Data Transfer and Use Agreement) terms into a subaward agreement. ATTACHMENT 7 DOES NOT REPLACE A DATA SHARING MANAGEMENT PLAN and should not be used for that purpose. For more information on Data Types, please click here for the FDP Tool for Classifying Human Subjects Data, and for information on which data types should be shared using a DTUA, please click here.

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:

How do I incorporate Attachment 7 into a subaward template?

First, Go to the FDP Subaward Forms website.

and then select the Cost Reimbursable Template.

<table>
<thead>
<tr>
<th>FDP Subaward Templates</th>
<th>Recommended use: domestic academic/non-profit institutions under federally funded grants or cooperative agreements.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resource</td>
<td>Version Date</td>
</tr>
<tr>
<td>Cost Reimbursable Template</td>
<td>December 2020</td>
</tr>
</tbody>
</table>
Second, go to Attachment 2 located in the Cost Reimbursable Template.

and complete the Human Subjects Data section of Attachment 2:

As shown above,

1. following “Human Subjects Data, (Select One)” select Applicable from the dropdown.
2. following “Human Subjects Data” will be exchanged under this Subaward:
   a. select “From Subrecipient to PTE” when the Subrecipient is providing the Data, or
   b. select “From PTE to Subrecipient” when the PTE is providing the Data, or
   c. select both when both parties are providing Data.
3. following “The PTE will set forth the terms of the exchange of Human Subjects Data (Select One)” select In Attachment 7 from the dropdown.

Third, open and complete Attachment 7, also located on the FDP Subaward Forms website.
As shown above,

1. following “Human Subjects Data will be exchanged under this Subaward (check all that apply)”
   a. select “From Subrecipient to PTE” when the Subrecipient is providing the Data, or
   b. select “From PTE to Subrecipient” when the PTE is providing the Data, or
   c. select both when both parties are providing Data.
   PLEASE BE MINDFUL TO ENSURE SELECTIONS MATCH SELECTIONS MADE IN ATTACHMENT 2!

2. As shown above (item # 2), following “The Data to be shared will be”
   a. select the applicable data type in the Dropdown. For more information on the data type options, see below and/or review The FDP Tool for Classifying Human Subjects Data, which is a tool designed to streamline review of the type of human subject data for the purpose of classification.
   - **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.
   - **Personally Identifiable Information (PII)**: Please refer to the FDP DTUA Project Glossary for definitions (found on the FDP Data Stewardship website). 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.
• **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](http://thefdp.org/default/assets/File/Documents/subaward_forms/DTUA-Subs_Guidance_FINAL_10_5_20.pdf) for a guide to determine when Limited Data Sets are being used.

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

• Select “Other” when the Data is a unique Human Subjects data set that requires protections, other than those found in the named data types in this drop-down menu. You will need to add the required protections for the unique data set to the description box under “Other” as terms will not auto-populate as they do for the other data types. 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.

b. Language applicable to that data type will auto populate in the page following the first page of Attachment 7.

c. If the data does not seem to autopopulate, hit enter again.

For more information on data types, please see the Attachment 7 FAQs (found at [http://thefdp.org/default/assets/File/Documents/subaward_forms/DTUA-Subs_Guidance_FINAL_10_5_20.pdf](http://thefdp.org/default/assets/File/Documents/subaward_forms/DTUA-Subs_Guidance_FINAL_10_5_20.pdf)) for guidance on the following scenarios:

- **Each Party is sharing a different data type (Question 11)**
- **Different Data types, but combining into one data set (Question 11.b)**
- **Data type unknown at subaward issuance (Question 10) – if the decision is to use a standalone DTUA see the main subaward template user guide on how to complete Attachment 2 to reflect this.**

3. As shown above (item # 4), following “Upon completion of the … Recipient shall retain or destroy the Data as instructed by the Provider; provided, however, that Recipient may retain one (1) archival copy of the Data”

   - select “Budget period End Date” or
   - select “Project Period End Date” as applicable for the needs of the project.
4. As shown above (item #5), enter a Description of Data in the text box or choose from the options below as applicable to the project.
   - The Provider may reference the IRB-approved protocol/survey in its description of the data, including via incorporating the protocol by reference. (Indicate if it is attached or provided separately/incorporated by reference.)
   - The Provider may also reference the Statement of Work (which is included as Attachment 5 in the subaward template).

5. As shown above, if the data type selected in Step 2 was “Other”, enter the required protections for the unique data set to the text box under “Other Terms and Conditions” as terms will not autopopulate as they do for the other data types. If there are no additional required protections, please be sure to enter NONE so that it is clear this section was not simply missed. (This box will not appear if anything but “Other” is selected in Step 2, otherwise, the applicable terms to the data type chosen will autopopulate.) Please refer to FAQ #6 for when Attachment 7 should not be used.
Other Terms and Conditions: Attachment 7 does not include other standalone DTUA language because it is already included in the subaward templates. Please see the FDP Subaward Template Attachment 7 PILOT FAQs (found on the FDP Subaward Forms website) for further information.

Additional resources:

- Attachment 7
- FDP Subaward Template Attachment 7 PILOT FAQs

Documents available on the FDP Data Stewardship website:

Stand-alone DTUA Templates or Samples (not to be included in the subaward agreement):

- One-way DTUA Template
- Reciprocal DTUA Template
- Collaborative DTUA Sample
- COVID-19 DTUA Sample

Helpful Tools:

- Sample DTUA Intake Checklist
- DTUA Guidance Chart - This chart is designed to provide guidance on when and how to use the FDP DTUA Template
- FDP DTUA Provider Guidance Chart - This chart is designed to provide guidance on selecting the most appropriate version of Attachment 2 when providing data via the FDP DTUA
- FDP Tool for Classifying Human Subjects Data - This tool is designed to streamline review of the type of human subject data for the purpose of classification for a DTUA.

Definitions and FAQs:

- DTUA Template - FAQs
- DTUA Glossary