

FDP USER GUIDE - SUBAWARD TEMPLATE ATTACHMENT 7

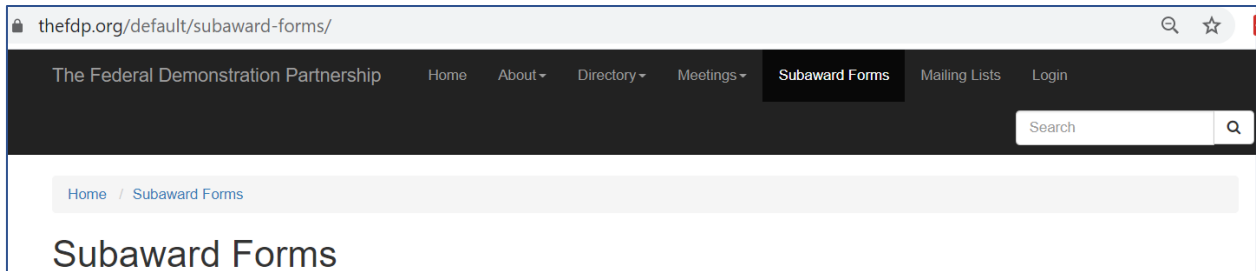
FOR ADDING HUMAN SUBJECTS DATA TRANSFER AND USE TERMS TO A SUBAWARD

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](#).

Subaward Templates, Samples, Tools & Resources: Overview

The FDP Subaward templates included below were designed to expedite and streamline federal subaward review among FDP member institutions. However, non-FDP members institutions may also use the templates. The templates are considered an ongoing FDP demonstration. Workgroups monitor federal developments and make necessary updates ([see our committee page for more information](#)). The templates are not meant to be edited.

Please keep in mind, however, that the FDP makes no representation or warranties regarding the suitability of these templates for use on any federal or non-federal sponsored projects. The pass-through entity (PTE) is responsible for ensuring all required terms and conditions flow down to a subrecipient. All users utilize these templates at their own risk.

The most recent version of the Research Terms & Conditions (RTC), which apply to research awards from a number of federal funding agencies, were approved in 2017. The RTCs are incorporated into the FDP Subaward templates and are also hosted by the NSF for all federal participating agencies here: <https://www.nsf.gov/awards/managing/rtc.jsp>

All templates, samples, tools, and resources are reviewed and updated, as needed, through the efforts of various working groups. Revised versions will be posted to this page in September, or as needed to address changes in Federal requirements. Please check here for the most recent versions before using the templates.

For more information, please review the guidance documents and FAQs provided below. If you cannot find the relevant information, please contact the Subawards Subcommittee co-chairs at subawards@thefdp.org.

TEMPLATES & SAMPLES

<i>FDP Subaward Templates</i> . Recommended use: domestic academic/non-profit institutions under federally funded grants or cooperative agreements.		
Resource	Version Date	Comments
Cost Reimbursable Template	December 2020	This 2020 release implements updates as required by changes to Uniform Guidance, as outlined and detailed in the crosswalk and major changes documents, both of which are located below in the supporting documents section of this page.
Fixed Amount Template		
Attachment 3B; Page 1 and Page 2		

Second, go to Attachment 2 located in the [Cost Reimbursable Template](#).

Attachment 2

Federal Award Terms and Conditions

and complete the Human Subjects Data section of Attachment 2:

Human Subjects Data (Select One) Applicable	
Human Subjects Data will be exchanged under this Subaward (check all that apply):	The PTE will set forth the terms of the exchange of Human Subjects Data (Select One):
<input checked="" type="checkbox"/> From Subrecipient to PTE <input checked="" type="checkbox"/> From PTE to Subrecipient	In Attachment 7.

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](#).

TEMPLATES & SAMPLES		
<i>FDP Subaward Templates</i> . Recommended use: domestic academic/non-profit institutions under federally funded grants or cooperative agreements.		
Resource	Version Date	Comments
Cost Reimbursable Template	December 2020	This 2020 release implements updates as required by changes to Uniform Guidance, as outlined and detailed in the crosswalk and major changes documents, both of which are located below in the supporting documents section of this page.
Fixed Amount Template		
Attachment 3B; Page 1 and Page 2		
Attachment 3A		
Attachment 7 Data Transfer and Use (DTUA) PILOT	January 2020	Attachment 7 is a PILOT developed in coordination with the FDP data stewardship subcommittee. FDP members are NOT required to use or accept Attachment 7 in their subawards.
Bilateral Subaward Amendment Free Text Only	December 2020	This 2020 release updates several fields, as outlined and detailed in the crosswalk and major changes documents, both of which are located below in the supporting documents section of this page. The bilateral amendment with pre-set options and text is designed for institutions to either have more consistency in amendment language and/or making it easier to program amendments into an online system.
Bilateral Subaward Amendment Template with pre-set options and text		
Unilateral Subaward Amendment Template		
<i>Foreign Subaward Samples</i> . Recommended use: foreign institutions under federally funded grants or cooperative agreements.		
Foreign Subaward Sample Cost Reimbursable	February 2021	Please note that these samples should be revised according to your institution's policies and in accordance with the needs and location of the research project, etc. We strongly advise consultation with the appropriate institutional officials to ensure any subaward meets institutional, sponsor and project requirements.



Attachment 7

Human Subjects Data Transfer and Use Terms

Human Subjects Data (“Data”) will be exchanged under this Subaward (check all that apply):

- From Subrecipient to PTE
- From PTE to Subrecipient

1. The Party providing the Data will be referred to as the “Provider,” and the Party receiving the Data will be referred to as the “Recipient” as reflected above in this section.

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!

- 1. The Party providing the Data will be referred to as the “Provider,” and the Party receiving the Data will be referred to as the “Recipient” as reflected above in this section.
- 2. The Data to be shared will be Select One
- 3. Provider authorizes Recipient Select One data sharing plan for this project, as may be required by the Recipient’s Institutional Review Board (IRB) and this Agreement.
- 4. Upon completion of the Budget for this project, the Recipient shall retain, protect, use, or destroy the Data as instructed by the Provider; or the Recipient shall retain, protect, use, or destroy the Data as instructed by the Provider. Protected Health Information (PHI) or destroy the Data as instructed by the Provider. Personally Identifiable Information (PII) or destroy the Data as instructed by the Provider. Limited Data Set (LDS) or destroy the Data as instructed by the Provider. De-Identified or destroy the Data as instructed by the Provider. Other (see description below) or destroy the Data as instructed by the Provider. (1) archival copy or destroy the Data as instructed by the Provider. Optional or destroy the Data as instructed by the Provider.
- 5. Description of Data (Describe the Data in detail, including the purpose of the Data, the source of the Data, and any other information relevant to the Data. (Optional))

- 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](#) 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](http://thefdp.org/default/assets/File/Documents/subaward_forms/DTUA-Subs_Guidance_FINAL_10_5_20.pdf) (found at 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.	Provider authorizes Recipient to share the Data as may be required under the data sharing plan for this project, as may be required by the Data Sharing & Access section of this Agreement.
4.	Upon completion of the <input type="text" value="Budget Period End Date"/> Recipient shall retain or destroy the Data as instructed by the Provider of the Data. Recipient may retain one (1) archival copy of the Data.
5.	Description of Data (Describe the Data, if not categorized as “Other” above; Optional otherwise): <input type="text" value="Project Period End Date"/>

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.

of the Data

5. Description of Data (Description is required if data is categorized as "Other" above; Optional otherwise):

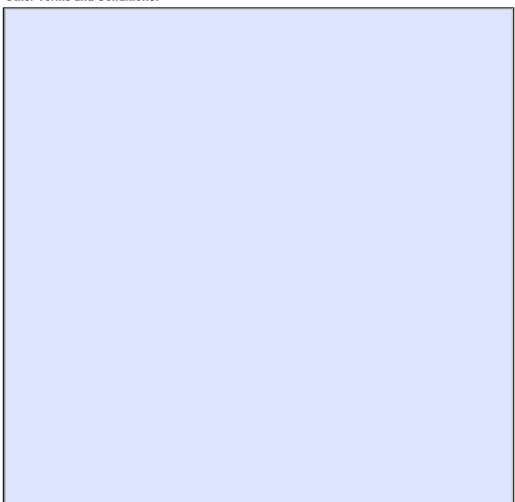
Description of Data:



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).

Other Terms and Conditions:



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 Documents available on the Subaward Forms website:
- [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](#)