



FDP Data Transfer and Use Agreement (DTUA) Pilot Frequently Asked Questions (FAQs)

1. Can I use the template even if my organization is not participating in the pilot and/or is not an FDP member organization?

Yes! We welcome all organizations, whether participating in the pilot or not, to use the DTUA template when appropriate. Such organizations are encouraged to use the [FDP DTUA Qualitative Questionnaire](#) to provide feedback on their experience with the DTUA template if willing.

2. Does participation in the pilot require me to make any changes in my organization's policies regarding when a DTUA is needed or use the DTUA in any situations where I ordinarily would not have an agreement in place?

No! Please see the [FDP DTUA Guidance Chart](#) for guidance on when a DTUA may be needed, subject to your own organization's policies. The goal of this effort is to streamline negotiations when the parties determine that a DTUA is necessary, not to suggest that a DTUA would be needed when the parties would otherwise agree that the data can be shared without an agreement in place.

3. What is the purpose of the Pilot?

To focus attention from early adopters on where and how the forms best accomplish their purposes and to gather information about those accomplishments. Resulting information will be used to confirm whether the template has the desired outcome of reducing the administrative burden of data sharing as well as what changes to the templates and/or methods of use may be needed to optimize the benefits.

4. When am I required to use the FDP DTUA Template as a participant in the Pilot? Can we still use our own DTUA templates during the Pilot?

Pilot participants will be expected to use the FDP DTUA template for stand-alone DTUAs only (not when data transfer and use terms are incorporated into another type of agreement such as a subaward, MTA, or unfunded collaboration agreement). The FDP DTUA template is intended for use when there is data flowing in a single direction, from Provider to Recipient. The template is not designed for use when sharing data from a repository or where third party rights inconsistent with the language of the template are likely to attach to the data.

We strongly encourage use of the FDP DTUA template with other nonprofits that are not FDP member organizations, when possible. When the Pilot participant is the Provider and the data type is either de-identified or a Limited Data Set, use of the FDP DTUA as at least a starting point is required in order to participate in the pilot; we will collect data on the modifications requested/required in these examples. When the Pilot participant is the Recipient, the organization must agree to accept the FDP DTUA when received and must at least encourage the Provider to use the FDP DTUA template. We will collect data on these examples as well. See below for a summary of when pilot use of the FDP DTUA template is required:



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<u>Pilot Participant is...</u>	<u>Other Party is a...</u>	<u>Data Type</u>	<u>FDP DTUA use is...</u>
Provider	FDP member or other domestic low-risk non-profit	De-identified or LDS	Required
Provider	FDP member organization or other domestic low-risk non-profit	PII covered by a published Attachment 2	Optional (but encouraged)
Provider	Foreign or For-profit entity or a domestic non-profit determined to be high risk	Any data type	Not Required; use of modified DTUA template permitted if FDP moniker removed
Provider or Recipient	Any Organization	Data subject to third party rights or other regulations not covered by existing DTUA template components	Not Required; use of modified DTUA template permitted if FDP moniker removed
Recipient	FDP Member Organization or other low-risk domestic non-profit	De-identified or LDS	Required to ask Provider if they'll use the template; use not required but strongly encouraged
Recipient	FD Member Organization of other low-risk domestic non-profit	PII covered by a published Attachment 2	Not Required; encouraged to ask Provider if they'll use the template
Recipient	Foreign or For-profit entity or a domestic non-profit determined to be high risk	Any data type	Not Required; use of modified DTUA template permitted if FDP moniker removed

5. What metrics am I required to track for my organization's DTUAs and how will I report these metrics to FDP?

Pilot participants are required to use the FDP DTUA Template Pilot Metrics Reporting Spreadsheet available via the [Data Stewardship](#) and [Contracts](#) website pages to submit quantitative data on a quarterly basis. For 1-3 DTUAs per month, Pilot participants are asked to complete the [FDP DTUA Qualitative Questionnaire](#) for collection of qualitative metrics. We also plan to seek feedback from Pilot participants on their experiences and template usability via two surveys: one at the halfway point and one at the completion of the pilot.



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6. How long will the pilot run? How long do we need to keep track of our DTUAs? Should we track DTUAs that were issued prior to the start of our participating in the Pilot but not yet fully executed?

We anticipate that the pilot will run for 12 months, but we may extend the pilot if necessary to collect sufficient data or end early if sufficient data is collected prior to the end of the 12 months. Pilot participants will be expected to track their organizations DTUAs for the duration of the Pilot but should not include any DTUAs initiated prior to the start of the pilot in their tracking.

7. What about if I need to insert special terms and conditions as a Pilot Participant?

If use of the FDP DTUA template is required per the chart in Question 4 above, insertion of terms that conflict with the standard terms or where a form field has not been specifically provided is not compliant with the rules of the pilot. When use is not required in the chart above, the template may be modified to meet the needs of the specific scenario as long as the FDP moniker is removed (or, you may choose to use a different template). In such a case, if the other party is another Pilot Participant, the reason for the exception should be noted in the transmission letter/email.

8. Where can I access information about the other FDP DTUA Pilot Participant Organizations?

The Pilot Planning Working Group obtained permission from the participating organizations to include their organization name on a list of participating organizations published with the other pilot materials on the FDP website. The [FDP DTUA Pilot Participating Organizations](#) list includes the name of the Participating Organization as well as the name and email address for the main Pilot Point-of-Contact at each Organization.

9. How were the initial Pilot Organizations chosen? Will there be an opportunity for additional organizations to join the Pilot?

An email was sent to all [FDP Administrative Representatives](#) on April 12, 2018 with a request to indicate their organization's interest in participation in the pilot by May 9, 2018. Interested organizations were also asked to provide information on volume of DTUAs and current average turn-around time. This information was used by the pilot planning working group to ensure that a representative cross-section of FDP member organizations was included in the pilot. Organizations were asked to formally commit to pilot participation a few weeks prior to the formal kick-off of the pilot on November 1, 2018.

Additional organizations are invited to participate in a second cohort at the six-month mark, beginning May 1, 2019. If your organization is interested in joining the pilot as part of this second cohort, please email the DTUA Pilot Working Group co-chairs at Melissa_Korf@hms.harvard.edu and mrdavis@brandeis.edu by April 24, 2019 to notify the working group of your interest. You will be sent a FDP DTUA Pilot Participation Agreement for review by your organization; signed Participation Agreements must be returned by April 30, 2019 in order to participate in the second cohort of the Pilot.

We welcome all organizations, whether participating in the pilot or not, to use the DTUA template when appropriate. If your organization is not formally participating in the pilot, you can provide feedback on your experiences via the [FDP DTUA Qualitative Questionnaire](#).



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10. How will information gathered during the Pilot and the Pilot results be shared back with the Pilot participants and the FDP community?

Updates will be provided during sessions at the FDP meetings and via emails to the Contracts and Data Stewardship listservs. The DTUA Pilot Working Group is also tentatively planning to host a webinar after the half-way point in May 2019 to share preliminary results with the community.

11. What resources will be provided to assist with implementation and learning about the template?

A variety of resources regarding the DTUA Template and Pilot are available via the [Data Stewardship](#) and [Contracts](#) website pages.

12. What are my organization's obligations upon formally agreeing to participate in the Pilot?

1. Use the template as set forth in the response to Question 4 above.
2. Determine who in your organization will be responsible for completing and turning in the questionnaire and quarterly data submission
3. Submit the requested data as required.

13. What if another one of the Pilot organizations issues my organization a DTUA that is not on the template? Or, what if I want to ask an organization that is not part of the Pilot or an FDP member organization to use the FDP template when my organization is the recipient?

The below sample language may be used when encountering one of these scenarios, but we also encourage modification as necessary to fit your organization's requirements and/or specific scenario.

If both data provider and receiver are pilot participants:

Dear Colleague,

[Providing Party Organization Name] and [Receiving Party Organization Name] are both participants in the Data Transfer and Use Agreement (DTUA) Template Pilot, a Federal Demonstration Partnership (FDP) initiative which aims to reduce the administrative burden associated with the transfer/sharing of research data. As a condition of participation, members agree to utilize the DTUA templates when sharing de-identified data about human subjects or Limited Data Sets with FDP member organizations or other low-risk domestic non-profits.

As our organizations are both participating in the pilot and we are sharing [de-identified data about human subjects or a Limited Data Set], we respectfully request that we use the DTUA template to share this data set. Further information regarding the pilot, guidance documents, and the template may be obtained at <http://thefdp.org/default/committees/research-compliance/data-stewardship/>.

Thank you in advance for your consideration and cooperation.
Sincerely,



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If only the receiver of the data is a pilot participant:

Dear Colleague,

[MY Organization Name] respectfully requests that the FDP Data Transfer and Use Agreement (DTUA) template be used to share this data set. [MY Organization Name] is participating in the DTUA Template Pilot, a Federal Demonstration Partnership (FDP) initiative which aims to reduce the administrative burden associated with the transfer/sharing of research data. The DTUA working group developed templates which are useful when sharing de-identified data about human subjects or Limited Data Sets. Further information regarding the pilot, guidance documents, and the template may be obtained at <http://thefdp.org/default/committees/research-compliance/data-stewardship/>.

[MY Organization Name] appreciates your consideration of this request to use the FDP DTUA templates.
Sincerely,

Sample Informational Paragraph when sending the DTUA template:

Dear Colleague,

[MY Organization Name] respectfully requests that we use the FDP Data Transfer and Use Agreement (DTUA) template to share this data set. My organization is participating in the DTUA Template Pilot, a Federal Demonstration Partnership (FDP) initiative which aims to reduce the administrative burden associated with the transfer/sharing of research data when the data is required to be controlled by law, regulation, or organizational policy. The DTUA working group developed templates which are useful when sharing de-identified data about human subjects or Limited Data Sets. Further information regarding the pilot, guidance documents, and the template may be obtained at <http://thefdp.org/default/committees/research-compliance/data-stewardship/>.

Sincerely,