

REQUEST TO ENTER INTO AN FDP PILOT

REQUEST DATE:	October 16, 2018
APPROVED BY THE EXECUTIVE COMMITTEE?	Pilot received Executive Committee approval on October 18, 2018.
TITLE OF PILOT:	Data Transfer and Use Agreement (DTUA) Template
REQUESTING GROUP:	Data Transfer and Use Agreement Working Group Research Administration Committee, Contracts Subcommittee Research Compliance Committee, Data Stewardship Subcommittee
APPROVED BY THE STANDING COMMITTEE CO- CHAIRS?	Yes
CONTACT INDIVIDUALS:	Melissa Korf, Harvard University (Melissa.Korf@hms.harvard.edu) Martha Davis, Brandeis University (mrDavis@brandeis.edu)
BACKGROUND AND SUPPORTING INFORMATION:	<p>Discussions among FDP member organizations revealed that the volume and complexity of Data Transfer and Use Agreements (DTUAs) executed to share research data are increasing. When every data provider uses a different agreement, significant time must be spent reviewing widely varying agreement terms during the negotiation (much as was the case with MTAs when the UBMTA was developed).</p> <p>The existence of a low-burden method for sharing data that cannot be made publicly available will be especially critical in helping organizations comply with sponsors' data sharing requirements. For example, the Proposed Provisions for a Draft NIH Data Management and Sharing Policy recently published by NIH (see NIH Guide Notice NOT-OD-19-014) specifically references data sharing agreements as a requirement that would need to be addressed in Data Management and Sharing Plans (see section IV.6). A streamlined agreement that facilitates broad sharing and re-use of research data while ensuring appropriate security and privacy considerations are addressed will facilitate compliance with these types of sponsor requirements.</p> <p>The DTUA template has been created as a first step towards creating greater consistency in terms and format to reduce associated administrative burden. The DTUA Working Group included at least one representative from approximately 30 member organizations and 2 individuals from Federal agencies. In the initial drafting stage, the working group reviewed 15 sample DTUAs provided by member organizations and leveraged language and formatting from other widely accepted templates, such as the Universal Biological Material Transfer Agreement (UBMTA) and the FDP Research Subaward Agreement.</p> <p>In the course of developing the template components, each document was shared broadly with the FDP membership for feedback. Many organizations routed the documents for additional internal review to provide comprehensive feedback. Where possible, this feedback has been incorporated into the final, published template documents.</p> <p>By moving the DTUA into a formal pilot phase, we hope to accomplish two goals:</p> <ol style="list-style-type: none"> 1) To confirm whether the template has the desired outcome of reducing the administrative burden of data sharing and 2) Collect feedback on what, if any, changes to the templates and/or methods of use may be needed to optimize the benefits.

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<p>BRIEF DESCRIPTION OF PILOT:</p>	<p>Pilot Participants will be expected to use the FDP DTUA template when they are the Provider of de-identified data or a Limited Data Set to another FDP member organization or other domestic low-risk non-profit. We recognize that the Recipient in a DTUA often has far less control in determining the format of the agreement to be used. However, when Pilot Participants are the Recipient of de-identified data or a Limited Data Set from another FDP member organization or other low-risk domestic non-profit, the Pilot Participant must agree to at least request that the Provider use the FDP DTUA template. In other data sharing scenarios, use of the DTUA template is not required, but Pilot Participants may choose to use the DTUA template if appropriate or may use a modified version of the DTUA template if the FDP moniker is removed.</p> <p>We are asking Participants to commit to use of the DTUA template beyond just other Participants to ensure that sufficient data is obtained. Unlike other pilots, such as the Expanded Clearinghouse, it is very difficult to anticipate whether Participants will need to enter into a DTUA with other Participants in a given year. Additionally, the qualitative information we will gather from Participants regarding their experiences using the template with non-Participants (see information on our metrics collection instruments) will be critical to the working group’s efforts to update the templates to be useful to as broad of an audience as possible.</p> <p>Participants will provide quarterly quantitative data regarding the volume and turn-around time of all DTUAs and periodically complete a Qualtrics questionnaire to provide feedback on usability of the templates, including terms that regularly need to be modified, added, or deleted during negotiations. The Qualtrics questionnaire will also be made available to organizations who are not formal Pilot Participants to ensure that feedback is obtained from as broad of a potential user base as possible.</p>
<p>SIGNIFICANCE TO FDP:</p>	<p>This pilot seeks to test whether a standardized, streamlined DTUA template can be developed to meet the needs of the FDP membership and whether such a template helps to reduce the administrative burden associated with data sharing for research, while also ensuring good stewardship of the data and compliance with applicable laws and regulations. If successful, this pilot will demonstrate a more efficient DTUA model than in use today. If unsuccessful, valuable information will be learned that may help better target the road blocks to efficient data sharing. This information can in turn be shared with member organizations as well as agencies to help develop more effective approaches to data sharing.</p>
<p>PARTICIPANTS:</p>	<p>Approximately 30 FDP member organizations have previously expressed interest in participating. We plan to start with those 30 organizations as well as making a feedback questionnaire available more broadly. At the 6-month mark, we will evaluate whether additional organizations can/should be added. This determination would be based upon interest from additional member organizations as well as the volume of data obtained up to that point.</p> <p>Participants from FDP member organizations will be expected to:</p> <ul style="list-style-type: none"> • Use the FDP DTUA template and applicable attachments as outlined in the Pilot Participation Agreement signed by each participating organization. • Provide the contact information requested by the DTUA Working Group and notify the DTUA Working Group of updates as necessary

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	<ul style="list-style-type: none"> • Agree to the public posting of their organization’s name in a manner that identifies the organization as a participating member of the pilot. • Complete the quantitative metrics spreadsheet on a quarterly basis, complete the Qualtrics questionnaire for at least 1-3 DTUAs per month (if any have been executed in that month), and respond to other surveys or requests for feedback as requested by the DTUA Working Group periodically over the course of the Pilot. • Provide suggestions for improvement and participate in formal evaluations. • Participants will have the option to terminate their participation at any time with thirty (30) days’ written notice to the DTUA Working Group Co-Chairs. <p>The FDP DTUA Working Group will</p> <ul style="list-style-type: none"> • Develop and maintain all necessary user documentation, FAQs, surveys and reports • Use the qualitative feedback received to develop, maintain and enhance the DTUA Template • Coordinate communication among the participants and provide participants with regular updates and status reports on the pilot • Provide regular updates to the broader FDP community via information shared on the Data Stewardship and Contracts listservs and at regularly scheduled FDP meetings.
<p>PILOT TIMETABLE:</p>	<p>November 1, 2018 – October 31, 2019</p> <p>We anticipate the time period of the Pilot to be 12 months with evaluation at the 6-month mid-point that would lead to a decision to stop, refine, continue, or expand the pilot to a larger pilot or full demonstration that includes other FDP organizations. This decision would be based on the data obtained from Pilot Participants up to that point as well as interest expressed by other member organizations.</p>
<p>SUCCESS CRITERIA:</p>	<ol style="list-style-type: none"> 1. Participants are able to use the DTUA template without modification to share de-identified data or a Limited Data Set in compliance with applicable laws and regulations. 2. When the DTUA template is used, Participants are able to execute the agreement in a timelier manner.
<p>PLANS FOR EVALUATION:</p>	<ol style="list-style-type: none"> 1. Quantitative data to be collected quarterly via excel spreadsheet to determine volume and turn-around time for various DTUAs. 2. Qualitative data will be collected to gauge usefulness and usability of the templates and collect feedback on what, if any, changes are needed to enhance the usefulness. 3. An additional survey may be administered up to twice during the period of the Pilot. 4. A report will be prepared at the end of the pilot recommending next steps.
<p>EARLY TERMINATION PLAN:</p>	<p>Continuous evaluation will take place throughout the pilot phase. At any point during the pilot if things are not going well or the process is causing undue complications for the pilot organizations the working group will review for possible termination. A summary report of activity and supporting justification will be provided to the Executive Committee for concurrence prior to official termination.</p>