

FDP Data Stewardship Subcommittee

Updates for May 2018 FDP Meeting Presenters:

Melissa Korf, Harvard University Martha Davis, Brandeis University



DTUA Template:

- Updates on current progress
- discussion of additional template components and/or guidance documents that would be useful

• DTUA Pilot:

- Updates on current status of planning
- discussion of current proposed requirements of participation in DTUA pilot
- Open discussion on suggestions for additional projects/demonstrations for this subcommittee



FDP DTUA Template Development

- Why did we start this project in the first place?
 - When every data provider uses a different agreement, significant time must be spent reviewing widely varying agreement terms during the negotiation. The DTUA template has been created as a first step towards creating greater consistency in terms and format to reduce associated administrative burden. This will be especially critical in helping institutions comply with sponsors' data sharing requirements.



FDP DTUA Template Development

- Incorporating institution-specific terms into the template (beyond appropriate sections of Attachments 1 or 3) defeats the purpose of the project.
- The working group has carefully drafted the language in the template to mitigate the concerns each institution has when acting as the Provider while ensuring that each institution would be able to easily accept the language when acting as the Recipient.



- Documents currently published:
 - DTUA Face Page
 - Attachment 1: Project Specific information
 - Attachment 2: Data-specific Terms and Conditions
 - De-identified Data about Human Subjects
 - Limited Data Set
 - Attachment 3: Identification of Permitted Collaborators (if any)
 - DTUA Glossary
 - DTUA Guidance Chart
 - Tool for Classifying Human Subject Data



- Documents under development
 - Attachment 2: Data-specific Terms and Conditions
 - Personally Identifiable Information Common Rule Only
 - Personally Identifiable Information HIPAA
 - Personally Identifiable Information FERPA
 - Why use the term Personally Identifiable Information (PII) in all three?
 - PII is a broader term that encompasses Protected Health Information (PHI) as well as other personally identifiable information



Questions, Comments, Concerns, Suggestions??



Background:

- A working group has been convened to plan and implement a formal pilot of the DTUA template.
- Initial request for indication of interest was sent to Administrative Representatives with request for response this week.
- Pilot is still in the planning phase. We hope to complete planning by August 2018 so that the pilot can formally begin in early Fall 2018.

What will a Pilot Do?

 Information collected 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.



What are the goals of the pilot?

 Information collected 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.



Pilot data collection methods:

- 1. Metrics Spreadsheet, submitted quarterly
- 2. Questionnaire completed once or twice a month noting details of one specific template use case
- 3. Survey, completed quarterly

Resources that are on the to-do list:

- 1. FAQs
- 2. PowerPoint presentation
- 3. Webinar

Suggestions are welcome!!

Metrics Data Collection Spreadsheet Example

DATA TRANSFER AND USE AGREEMENT (DTUA) TEMPLATE TRACKING FORM										
REPORTING ENTITY NAME:						R	EPORTING PERIOD:			
REPORTING CONTACT NAME:						LAST UPDATED:				
REPORTING CONTACT EMAIL ADDRESS:										
TOTAL NO. DTUAs EXECUTED THIS QUARTER: :										
				Choose "1" or "0" from the drop list						
DTUA NUMBER AT PARTICIPANT ORGANIZATION (OPTIONAL)	RECEIVER NAME	RECEIVER TYPE	ISSUE DATE	FULLY EXECUTED DATE	FDP DTUA USED - NO MODIFICATION	FDP DTUA USED - WITH MODIFICATION		SPECIFY WHICH ATTACHMENT 2 USED	NOTES/COMMENTS (OPTIONAL)	



Sample FAQs

- Q7. Can I use the template even if my institution decides not to be part of the pilot?
- A. Yes! We welcome all institutions, whether participating in the pilot or not, to use the DTUA template when appropriate.
- Q8. Will participation in the pilot require me to make any changes in my institutional policies regarding when a DTUA is needed or use the DTUA in any situations where I ordinarily would not have an agreement in place?
- A. No! Please see the <u>FDP DTUA Guidance Chart</u> for guidance on when a DTUA may be needed, subject to your own institutional policies. The goal of this effort is to streamline negotiations when the parties determine that a DTUA is necessary, <u>not</u> 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.
- Q11. 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?
- A. 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 also not designed for use when sharing data from a repository, where third party rights are likely to attach to the data, and is intended for use when there is data flowing in a single direction, from Provider to Recipient.

FDP DTUA Template Pilot

FDP DTUA Pilot Requirements Chart

Pilot Participant is	Other Party is a	Data Type	FDP DTUA use is
Provider	FDP member institution or other domestic low-risk non-profit	De-identified, LDS, or PII covered by published Attachment 2	Required
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 Institution	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 Institution or other low-risk domestic non-profit	De-identified, LDS, or PII covered by published Attachment 2	Required to ask Provider if they'll use the template; use not required but strongly encouraged
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



Data Transfer and Use? No Problem, Piece of cake with the FDP template!



Questions and Comments



Data Stewardship: Other Projects??

