Data Stewardship Subcommittee

FDP Meeting
January 10, 2020

<u>Presenters and FDP DTUA Working Group Co-Chairs</u>:
Melissa Korf, Harvard University
Martha Davis, Brandeis University



- FDP Data Transfer and Use Agreement (DTUA) Preliminary Pilot Results
- DTUA Template progress and upcoming goals
- Draft NIH Policy for Data Management and Sharing and Supplemental Draft
 Guidance – opportunities for new projects/working groups?

DTUA Pilot Update

- Pilot period: 11/01/18 10/31/19
- Quantitative data collected quarterly for 4 quarters
- Quantitative Information collected: Receiver Name, Receiver Type, Issue Date, Fully Executed Date, Type Agreement used (FDP DTUA Template with no modification, FDP DTUA Template with modification, or Non-FDP DTUA Template), and Data Type
- The initial wave included 30 participants; Wave 2, starting in May 2019, added 4 more participants

DTUA Pilot Goals

- Gather information on how the forms best accomplish their purposes and disseminate results
- Confirm whether the template has the desired outcome of reducing the administrative burden of data sharing
- Gather feedback on what changes to the templates and/or methods of use may be needed to optimize the benefits. If we find that the same terms need to be modified with great frequency, we will prioritize efforts to update those terms to increase effectiveness.



Preliminary Quantitative Results

Total Number of DTUAs Reported								
Quarters	FDP Template - Unmodified	FDP Template - Modified	Non-FDP Template	Total DTUAs				
Q1	87	6	203	296				
Q2	72	7	247	326				
Q3	107	14	255	376				
Q4	72	7	151	230				
Total	338	34	856	1228				



Preliminary Quantitative Results

Average Days Per DTUA Negotiation						
Quarters	FDP Template - Unmodified FDP Template - Modified		Non-FDP Template	Total DTUAs		
Q1	41	21	54	49		
Q2	49	19	47	47		
Q3	45	27	48	46		
Q4	49	66	71	64		
Total Average	46	32	53	51		



Preliminary Quantitative Results

Comparison of Average Days for FDP Template Negotiations vs. Non-FDP Agreements Negotiations

Quarters	FDP Template - Unmodified	Non-FDP Template	Difference	Percent Difference	Result
Q1	41	54	13	24%	24% less time when used FDP DTUA template vs Non-FDP DTUA agreement
Q2	49	47	-2	-4%	4% more time when used FDP DTUA template vs Non-FDP DTUA agreement
Q3	45	48	3	6%	6% less time when used FDP DTUA template vs Non-FDP DTUA agreement
Q4	49	71	22	│ 31%	31% less time when used FDP DTUA template vs Non-FDP DTUA agreement
Total Average	46	53	7	13%	13% less time when used FDP DTUA template vs Non-FDP DTUA agreement



Selected comments:

- "It was extremely helpful to suggest the DTUA template when they were not being receptive to negotiations."
- "It made it easier to have a broadly accepted agreement to start the negotiations."
- "Simplified and sped up the process."
- "There was no negotiation related to contract terms, but a great deal of logistics to work out for the project prior to signature."
- "People get confused on Attachment 3. They do not understand that 'collaborator' means a third party, an entity not party to the DTUA."
- Try to keep something like this active to facilitate provision of feedback post-Pilot?

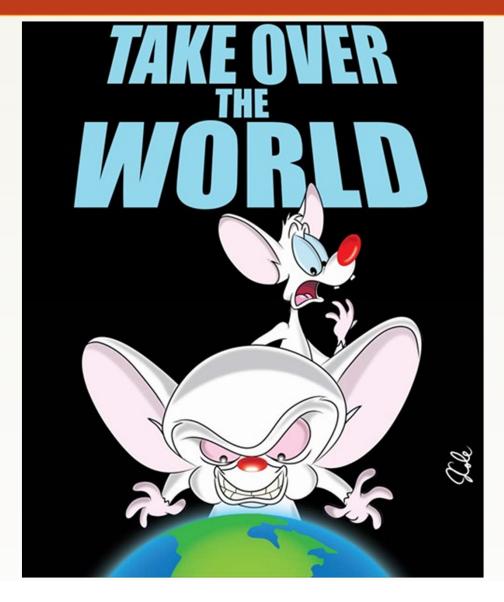


- Main issue is with institutions who are completing Attachment 3 incorrectly.
- Very few data transfers are actually "plain vanilla" so a multi-party, bi-directional template that facilitates collaboration would be helpful.
- Being able to say that the pilot phase is complete may facilitate adoption by some entities.
- Sometimes the negotiation may be quick but collecting the information necessary to complete the agreement adds delays to the process. An example intake questionnaire could be helpful.
- Might be helpful to have a word document sample that could be more easily modified for complex scenarios.



- Analyze quantitative and qualitative results in further detail
- Prepare white paper summarizing results and recommending next steps with the DTUA
- If you are interested in helping to analyze the data and/or write the white paper, please let us know!







DTUA Template Progress & Goals

- In collaboration with Subawards Subcommittee, finalized and posted Subaward <u>Attachment 7</u>, which can be used to incorporate DTUA terms into a subaward agreement.
 - Working to develop guidance materials to accompany Attachment 7 and will prepare and host a webinar to support use of the attachment.
- Distributed draft Collaborative DTUA for membership feedback.
 - Working to review feedback and incorporate as appropriate. Guidance materials to be created once Collaborative template is finalized.
- Suggestions for deliverables to add to our work plan?



- Comments due TODAY!
- Includes:
 - Draft policy
 - Supplemental Draft Guidance: Allowable Costs
 - Supplemental Draft Guidance: Elements of a Data Management and Sharing Plan



- Data Management and Sharing Plan (Plan) to be submitted at JIT rather than with the proposal.
 - Positive change?
 - How to help investigators consider costs of compliance in the budget if the plan is not developed until JIT?
- What changes to the Plan would/should be considered significant enough to require prior approval?
- Other NIH ICOs may supplement the policy as appropriate? How can we strive for consistency?
- Other thoughts?



- How could this subcommittee support compliance while minimizing administrative burden?
- Collaboration with Finance, Audit, and Costing to develop more detailed guidance on allowable costs?
- Collaborate with NIH to streamline requirements for submission to NIH-supported repositories?
- Other opportunities/suggestions?



Contact:

Melissa Korf
Director, Grants & Contracts
Office of Research Administration
Harvard Medical School
617-432-1247
Melissa_Korf@hms.harvard.edu

Martha Davis
Associate Director, Pre-Award
Office of Research Administration
Brandeis University
781-736-2169
mrdavis@brandeis.edu