



FEDERAL DEMONSTRATION PARTNERSHIP

Redefining the Government & University Research Partnership

FDP Data Stewardship Subcommittee Data Transfer and Use Agreement (DTUA) Template and Pilot

September 2018 FDP Meeting

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Session Agenda

Agenda

- DTUA Background
- Template Structure and Instructions for Use
- Goals of the Pilot
- “Rules” for the Pilot
- Pilot Timeline
- Discussion/Questions



So, what is a DTUA, anyway?

- A contractual agreement used to define how exchanged data may be accessed and/or used.
- These may have many different labels: Data Use Agreement, Non-Disclosure Agreement, Confidentiality Agreement, Memorandum of Understanding, Information Transfer Agreement, etc.
- Data Transfer and Use Agreement (DTUA) is the label chosen by the FDP to capture all agreements executed for the sharing of research data.



What do we mean by “research data”?

2 CFR 200.315(e)(3) defines research data as

“the recorded factual material commonly accepted in the scientific community as necessary to validate research findings, but not any of the following: preliminary analyses, drafts of scientific papers, plans for future research, peer reviews, or communications with colleagues. This “recorded” material excludes physical objects (e.g., laboratory samples). Research data also do not include:

- (i) Trade secrets, commercial information, materials necessary to be held confidential by a researcher until they are published, or similar information which is protected under law; and
- (ii) Personnel and medical information and similar information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, such as information that could be used to identify a particular person in a research study.”



DTUA Template Aims to Relieve Burden

- The volume and complexity of DTUAs executed to share research data are increasing.
- The DTUA template has been created as a first step towards improving quality and creating greater consistency in terms and format to reduce associated administrative burden.
- A low-burden method for sharing data that cannot be made publicly available will be especially critical in helping institutions comply with sponsors' data sharing requirements.



Current DTUA designed for these data sharing scenarios:

- The transfer/sharing of research data from the provider institution to a recipient institution for use in a research project at the recipient institution.
- Transfer/sharing of data types which do not require terms beyond those in the facepage, de-identified data about human subjects, or a Limited Data Set. (Versions which can be used in sharing Personally Identifiable Information will be forthcoming soon!)
- Currently **not** designed for bidirectional flow of data, use in transferring materials, sharing data from a repository, or where third party rights inconsistent with the template terms are likely to attach to the data.



DTUA Template Structure

- **Face Page** includes the information and terms that need to be incorporated into every DTUA, regardless of the data type.
- **Attachment 1** includes information related to the project specifics, such as a description of the data being transferred, a description of the Project for which use of the data is being authorized, and information regarding reimbursement of costs, if any is required.
- **Attachment 2** includes terms required based on the specific type of information being transferred, if any.
- **Attachment 3** includes information on the involvement of any third party collaborators approved by the Provider.



Where can I find the template?

- All template documents available on both the [Data Stewardship](#) and [Contracts](#) subcommittee pages
- Components Currently Available
 - [DTUA Face Page with Attachments 1 and 3](#)
 - [DTUA Attachment 2: De-identified Data about Human Subjects](#)
 - [DTUA Attachment 2: Limited Data Set](#)
 - [DTUA Attachment 2: Other](#)



How does the template work?

- Form-fillable pdf documents
- Included instructions to the drafter within the text boxes to indicate the type(s) of information intended to be included
- Language that is not included within a form text box should not be altered.

Walk through of the template documents



Pilot Time!





DTUA Pilot Goals

- Gather information on how the forms best accomplish their purposes
- 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 hear that the same terms need to be modified with great frequency, we will prioritize efforts to update those terms to increase effectiveness.



Metrics – Quarterly Report

- Information Collected

- DTUA reference number (optional)
- Receiver Name
- Receiver Type
- Issue Date
- Fully Executed Date
- Choose one from these options: FDP DTUA Used – No Modification, FDP DTUA Used – With Modification, or Non-FDP DTUA Used
- Data Type: De-identified or Limited Data Set
- Notes/Comments (Optional)



Qualitative Questionnaire

- On-line questionnaire that will be used to collect information how to enhance usability, such as:
 - Did any standard terms need to be modified? If so, which ones?
 - Is there any information you needed to include in Attachment 1 but could not place in an existing form field?
- Pilot participants will be expected to complete at least one per month in which the institution executes a DTUA
- Questionnaire will be made available to non-participants to collect feedback from a broad audience.



Pilot “Rules”

<u>Pilot Participant is...</u>	<u>Other Party is a...</u>	<u>Data Type</u>	<u>FDP DTUA use is...</u>
Provider	FDP member institution or other domestic low-risk non-profit	De-identified or LDS	Required
Provider	FDP member institution 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 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 or LDS	Required to ask Provider if they'll use the template; use not required but strongly
Recipient	FD Member Institution 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



DTUA Pilot Timeline

- Anticipated start date in October 2018
- Initial pilot expected to last 12 months
- Additional institutions may be invited to participate at the 6-month mark if sufficient interest
- Updates and results will be shared with the community at FDP meetings and via the Data Stewardship and Contracts listservs



DTUA Resources

- Currently Available:
 - [DTUA Glossary](#)
 - [DTUA Guidance Chart](#)
 - [Tool for Classifying Human Subject Data](#)
 - [DTUA Pilot FAQs](#)
- Coming Soon!
 - Template FAQs
 - Webinar (Recording to be posted on website)
 - DTUA 101 and Pilot slide deck
- With permission from Pilot Participants, we will also publish a list of participating institutions



Questions, Comments, Concerns, Suggestions??

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