UT Southwestern
Medical Center
Human Research Protection Program

Charting the Path to Scientific Collaboration: Navigating Research Data and Biospecimen Sharing and Agreement Requirements

Presented by:
Meyad Bird, BA, CIP
Kimberly Hawkins, BA, CIP

Discussion Topics

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- What is data/biospecimen sharing
- Regulatory requirements
- Protocol considerations
- Consent form considerations
- Data use/material transfer agreements

What is Data/Biospecimen Sharing?

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The practice of making research data/biospecimens available to others for purposes beyond the original study.

It involves providing access to the raw data, biospecimens, documentation, and other associated materials collected during a research project to enable other researchers to verify, reproduce, and build upon the findings.

Helpful to Science

Scientific Advancement – leading to new discoveries

Resource Efficiency – reduce need to conduct redundant studies

Educational Opportunities – provide resource to train/educate new researchers

- There are no restrictions on the use or disclosure of de-identified health information.
- A covered entity may not use or disclose protected health information, except either:
  - (1) as the Privacy Rule permits or requires; or
  - (2) as the individual who is the subject of the information (or the individual's personal representative) authorizes in writing.
- A covered entity is permitted, but not required, to use and disclose protected health information, without an individual's authorization, for the following purposes or situations:
  - (1) To the Individual (unless required for access or accounting of disclosures);
  - (2) Treatment, Payment, and Health Care Operations;
  - (3) Opportunity to Agree or Object;
  - (4) Incident to an otherwise permitted use and disclosure;
  - (5) Public Interest and Benefit Activities; and
  - (6) Limited Data Set for the purposes of research, public health or health care operations.
- Covered entities may rely on professional ethics and best judgments in deciding which of these permissive uses and disclosures to make.

Applicable Regulations

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45 CFR 46:

- The IRB needs to know that "when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data" [45 CFR 46.111(a)(7)]

21 CFR 50, 56

- The consent form must contain "A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the Food and Drug Administration may inspect the records." 21 CFR 50.25(a)(5)
- "Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data." 21 CFR 56.111(a)(7)

NIH Data Sharing Policy Requirements

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Data Management Sharing (DMS) Plan required for all new or competing renewal grant applications for receipt dated on or after January 25, 2023.

Data must be shared at the time of publication or at the end of the award, whichever comes first.

Applies to all research funded or conduced in whole or in part by NIH that results in the generation of scientific data.

Protocol Considerations

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- What will be shared?
- Why is data/biospecimen being shared?
- Who will the data/biospecimen be shared with?
- Does the data/biospecimen sharing mean that the recipient site is engaged in research?
- Data/biospecimen security
- Risks and mitigation strategies for data/biospecimen sharing
- Retention and disposal of data/biospecimen
- Returning research results
- NIH data sharing Requirements

What is being shared?

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De-Identified Data/Biospecimen

The data or biospecimen has been stripped of all private identifying information (PII) and/or protected health information (PHI)

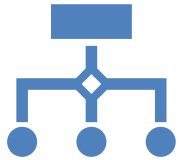
Coded Data/Biospecimen

The data or biospecimen has been stripped of all PII and/or PHI and has a code attached to the information.

If the recipient has access to the link to reidentify research participants then data or biospecimens must be treated as identifiable

Limited Data Set

The data has been stripped of all PII and/or most PHI but can contain dates or zip codes



Identifiable Data/Biospecimen

The data or biospecimen will be shared with one or more elements of PII and/or PHI

Why are the Materials Being Shared?

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- Include the purpose of data sharing in the protocol.
- This helps the IRB determine whether sharing aligns with the best interest of the research participants and whether the sharing advances scientific knowledge

With Whom is the Data to be Shared?

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- Include names/entities in which the data is to be shared.
- This helps the IRB determine whether sharing:
  - Has been properly disclosed in the consent and HIPAA authorization, or
  - Listed in the HIPAA Waiver request, and
  - Should the entity be external to the United States, that embargos are not in place with the entity

Is the Recipient Engaged in Research?

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- Consideration must be made:
  - On whether the recipient entity/collaborator will receive identifiable data/biospecimens
- If the recipient entity/collaborator will receive identifiable data/biospecimens, how will IRB approval be handled? It depends
  - sIRB or will recipient entity/collaborator obtain their own IRB approval

How will Data Security be Handled?

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- Safeguards in place while sharing the data and to prevent unauthorized access, breaches, or misuse
- Methods of transmitting the data/biospecimens to the external entity/collaborator

What are Risk Mitigation Strategies?

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Risks

- Privacy concerns - Disclosure of sensitive information can lead to breaches of privacy
- Data misuse/future research implications - materials may be used for unintended/unapproved purposes or by unauthorized parties
- Stigmatization/Discrimination – research participants may face social, legal, economic consequences if materials reveal sensitive information
- Cultural or Ethical considerations – some communities may have concerns about use of their materials in research

Mitigation Strategy

- Share in de-identified manner, where possible
- Ensure that Informed Consent/Authorization are clear about who the materials will be shared with and what they will be used for or that Data Use Agreements describe use
- Ensure that sharing the minimum necessary and additional safeguards in place
- The IRB may consult with cultural experts to ensure appropriate protections in place

How long will Materials be Retained/disposed?

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The protocol must include the duration for which materials will be available for sharing and establish procedures for disposition.

If there are no plans to dispose materials, assess whether the materials will be retained in a research repository

Returning Research Results to Participants

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- For federally funded research, researchers must have a plan for how and when to return results to research participants and to inform participants whether clinically relevant research results will be returned to them. Some points to consider include and IRB Considerations:
  - Whether the result would provide meaningful information to the health care provider
  - Whether it would have a significant impact on the health management decisions
  - Whether any impact would be critical and/or time-sensitive

NIH Data Sharing

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THE IRB MUST REVIEW THE DATA MANAGEMENT AND SHARING (DMS) PLAN TO ENSURE THAT THE PROTOCOL AND CONSENT FORM ARE CONSISTENT WITH THE PLAN.

THE IRB MUST ALSO REVIEW THE RISK ASSOCIATED WITH SHARING THE DATA OF PARTICIPANTS OR GROUPS.

THE IRB MUST REVIEW THE CONSENT FORM TO ENSURE DATA SHARING IS CONSISTENT WITH PROTOCOL AND DMS PLANS AND THAT RISKS HAVE APPROPRIATELY BEEN DESCRIBED.

Informed Consent/HIPAA Authorization

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- Statement of sharing and purpose
- How confidentiality will be maintained
- Risks and benefits of sharing
- Security measures
- Returning clinically relevant results

Returning Research Results to Participants

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Result	Plan	Information to Participant
• Information that is critical to the management of a participant's health in the immediate/near future.	• Immediately return information to the participant, and/or the participant's care provider if the participant agrees, so the participant can obtain appropriate healthcare.	• Any information that might be immediately critical to your health will be shared with you or your health care provider.

Returning Research Results to Participants

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Result	Plan	Information to Participant

• A known implication about health or risk, and are clinically actionable but not emergent (e.g., not severe or particularly time sensitive).	• Return these results if feasible and participant agrees. Considerations:
	  • resources to return results
	  • how you can facilitate next steps for participant's healthcare
		• We will share information that may be helpful for your health in the future: [genes/labs/images that may suggest you have an increased risk of [Condition]. Describe why this information is important to share. Include language for participants to indicate whether they want to receive the information.

Returning Research Results to Participants

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Result	Plan	Information to Participant

• Known implication about health or risk but are not clearly clinically actionable.	• Return results if participant agrees
	• Considerations:
	  • Risk of knowledge
	  • Actions that can be taken
	  • Resources to return results
	  • How you can facilitate next steps for participant's healthcare
		• During the study we will learn things about you that you may find interesting but will not help you. You may include a statement that indicates that health care professionals may not know what the information means or what to do about it. Describe why it may be helpful to know this information. Include language for participants to indicate whether they want to receive the information.

Returning Research Results to Participants

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Result	Plan	Information to Participant

• Results that do not have a known implication for health or risk.	• Plan to return results if participant agrees
	  • Considerations:
	  • If knowledge is of value
	  • Whether the participant is likely to understand information and implications
	  • Risks of knowledge
	  • Resources to return results
	  • How you can facilitate next steps for participant's healthcare
	• You may indicate that there are no plans to provide this information to the participant or their healthcare provider
		• During the study we will learn things about you that you may find interesting but will not help you. You may include a statement that indicates that health care professionals may not know what the information means or what to do about it. Describe why it may be helpful to know this information. Include language for participants to indicate whether they want to receive the information.

What are expectations at UTSW for sharing Human Data?

Consent for Sharing Obtained

1. Explicit consent for **Open Access**:
   - Identifiers should be removed
   - Consent must specify the **type and identifiability** of the data to be shared
   - Consent must specify that the sharing will be Open Access (allows anyone to access and use the dataset).

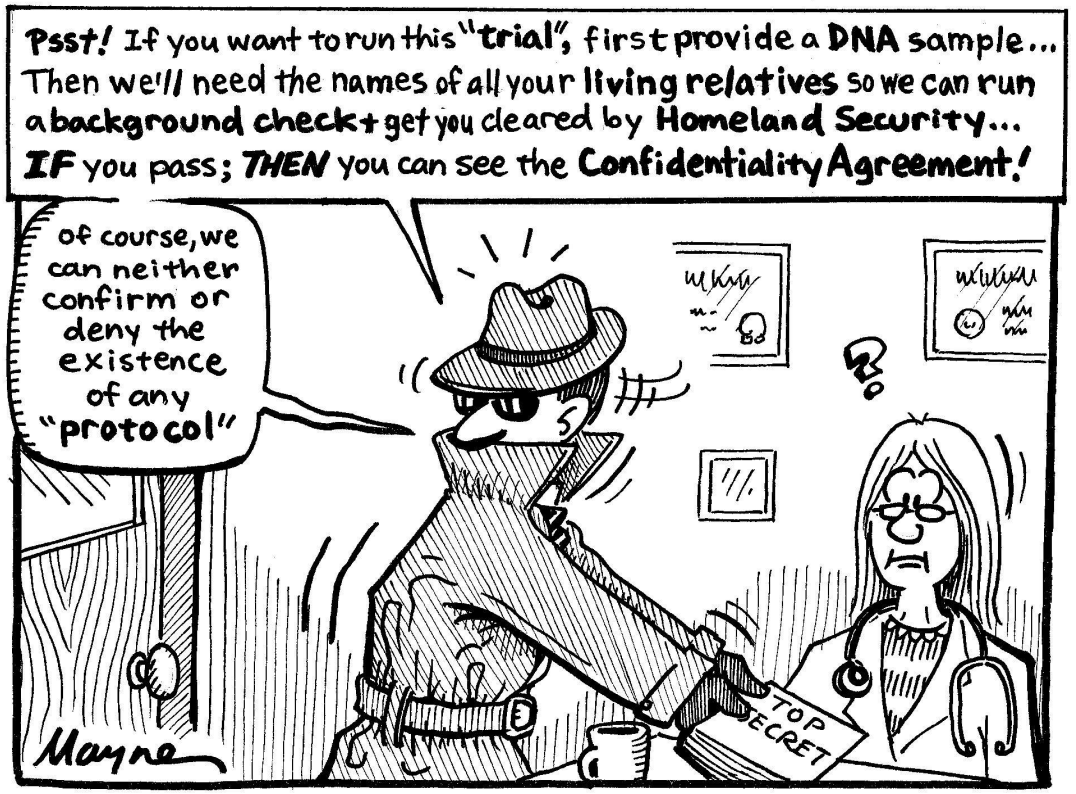
2. Explicit consent for **Controlled Access**:
   - Consent must specify the **type and identifiability** of the data to be shared
   - May need to specify required controls

Consent for Sharing Not Obtained

3. Consent Obtained (prior to 1/25/2023) but no mention of data sharing
   - Only deidentified or limited data sets may be shared
   - Only share to **controlled access** repository
   - May need to specify required controls

4. Consent waived by the IRB
   - Data must be deidentified
   - Only share to **controlled access** repository
   - May need to specify required controls

From: Oilepo, Rhonda. NIH Data Management and Sharing Policy Data sharing considerations: human research data. January 2023, https://www.utsouthwestern.edu/research/hrpp/assets/researchmatters_2023_01_stateofhrpp.pdf



DATA USE AGREEMENTS & MATERIALS TRANSFER AGREEMENTS

What is a Data Use Agreement (DUA)?

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- A DUA is a legally binding agreement that outlines the terms and conditions of data sharing, including restrictions on data use, sharing, and confidentiality.

- Elements:
  - Parties
  - Definitions
  - Terms
  - Data and Purpose

This Data Transfer Agreement ("**Agreement**") is between:

The University of Texas Southwestern Medical Center, a state institution of high education established under the laws of the State of Texas as a component of The University of Texas System, ("**UT Southwestern**"), on behalf of its investigator, ___ ("**Scientist**");

Dallas County Hospital District, doing business as Parkland Health ("**Parkland**"); and

___ ("**Recipient**"), on behalf of its investigator, Dr. ___ ("**Investigator**"), for the following use: ___ ("Research").

When is a DUA needed?

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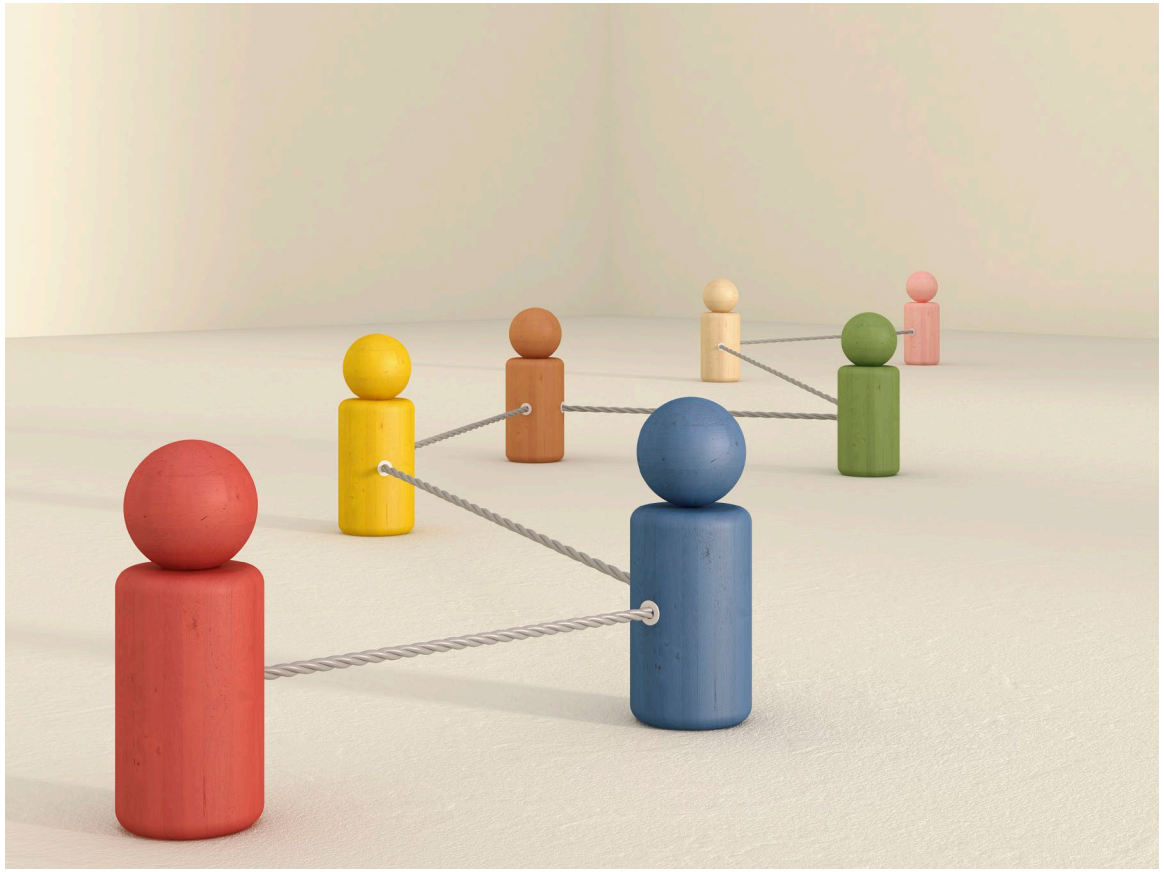

- Sharing de-identified data –
  - Agreement Type: Data Transfer Agreement (DTA) (select Data Use Agreement in eAgreements)
    - **Not-For-Profit Entity in the U.S.** - UTSW does not require a Data Transfer Agreement to provide de-identified data to a not-for-profit institution located in the United States but will provide one if the other organization requires an agreement.
    - **For-Profit Entity** - Reassigned to the Office of Technology Development
    - **International Entity** – Export Control Check

- Sharing a limited data set -
  - Agreement Type: Data Use Agreement (DUA)
    - **Not-For-Profit Entity in the U.S.** – DUA Required
    - **For-Profit Entity** - Reassigned to the Office of Technology Development
    - **International Entity** – Export Control Check

What is a Material Transfer Agreement (MTA)?

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- An MTA is a contract that governs the transfer of ***tangible research materials*** between two organizations when the recipient intends to use the materials for his or her own research purposes.
  - When is it needed?
    - Sharing research materials with or without data
- MTAs are processed by the Office of Technology Development (OTD). The HRPP provides an Ancillary Review of the IRB study.
- These are listed in eAgreements as “Multiple Material Transfer Agreements”.

eIRB Study Review for DUA/MTA

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Protocol

- Data sharing plans

Consent

- Procedures/HIPAA
- Reconsenting plans (for subjects not privy to sharing plans)

Modification may be required

- SmartForm Updates
- Other updates

For Modification that may be required:

Item 24.1.1a:

- List Agreement number,
- Where the data is planning to be shared: [Name of Organization],
- What data is planned to be shared: [De-identified or Limited Data Set]
- Indicate whether data will be **viewed** and/or **transferred** to the Organization
- **How** data is being viewed and/or transferred (e.g., REDCap, encrypted, password-protected Excel spreadsheet, Box, etc.)

Item 24.0 applies to data/specimens both sent and received even though it states "shipped".

How are DUA/MTAs submitted?

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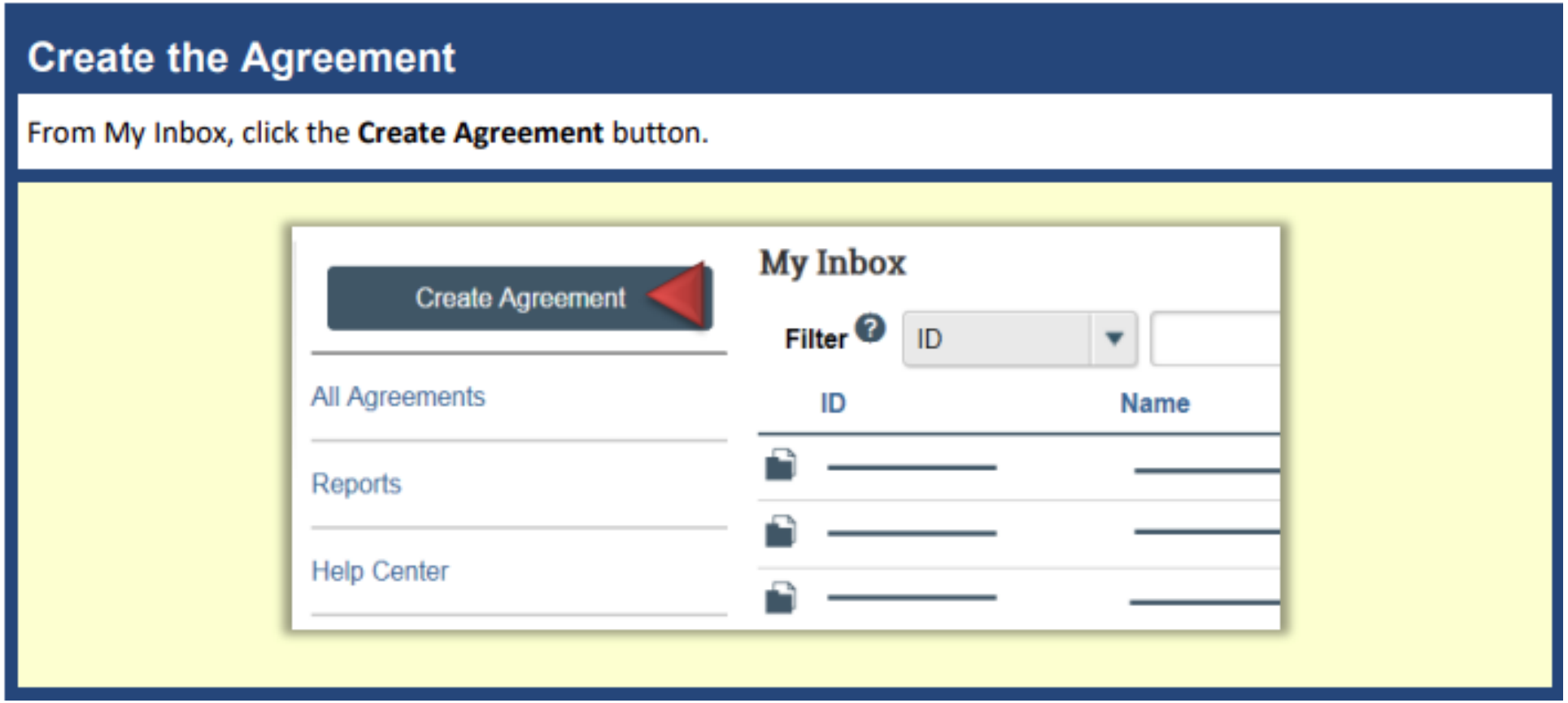
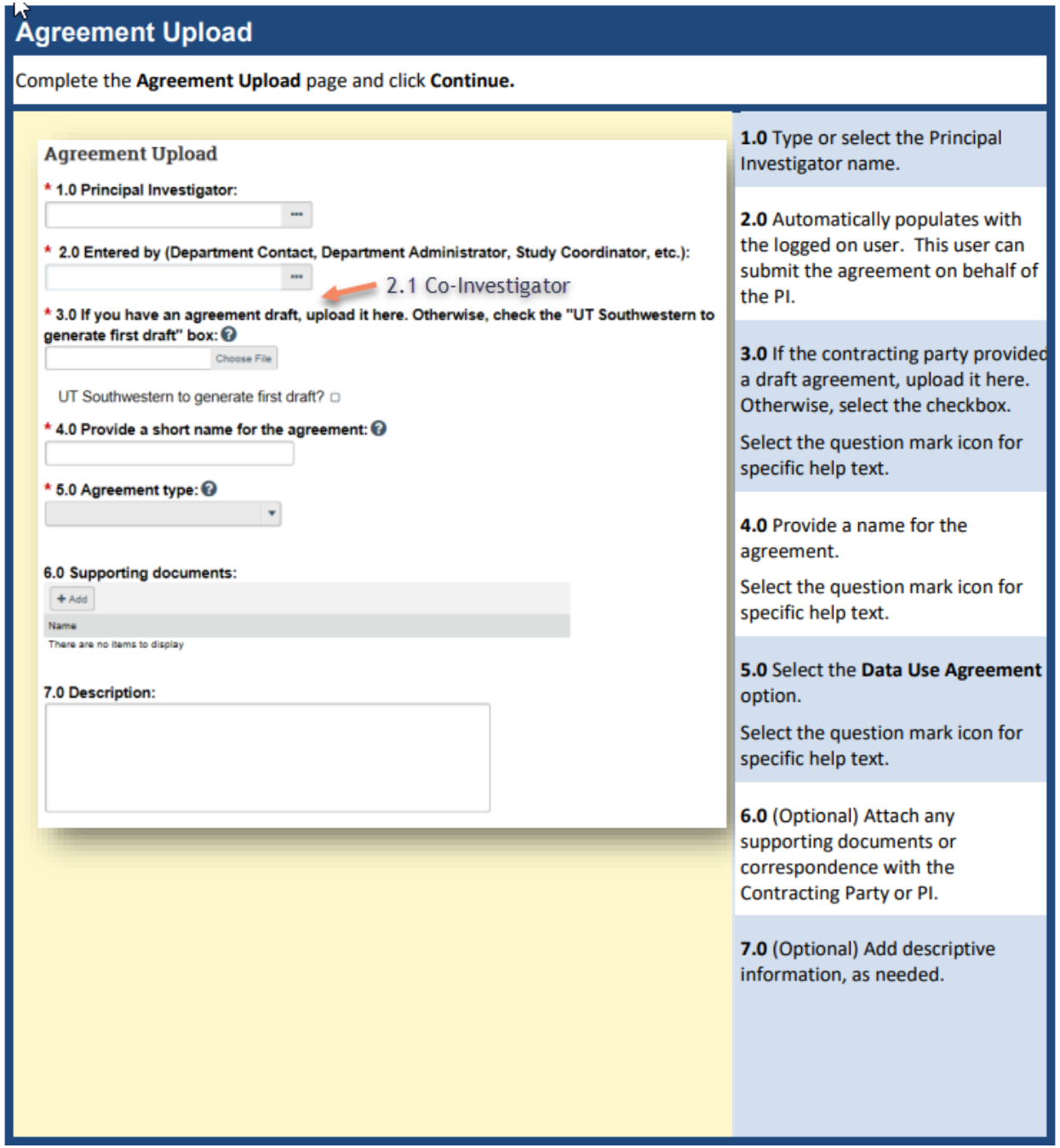
- DUAs/MTAs are submitted in eAgreements by selecting “Create Agreement”





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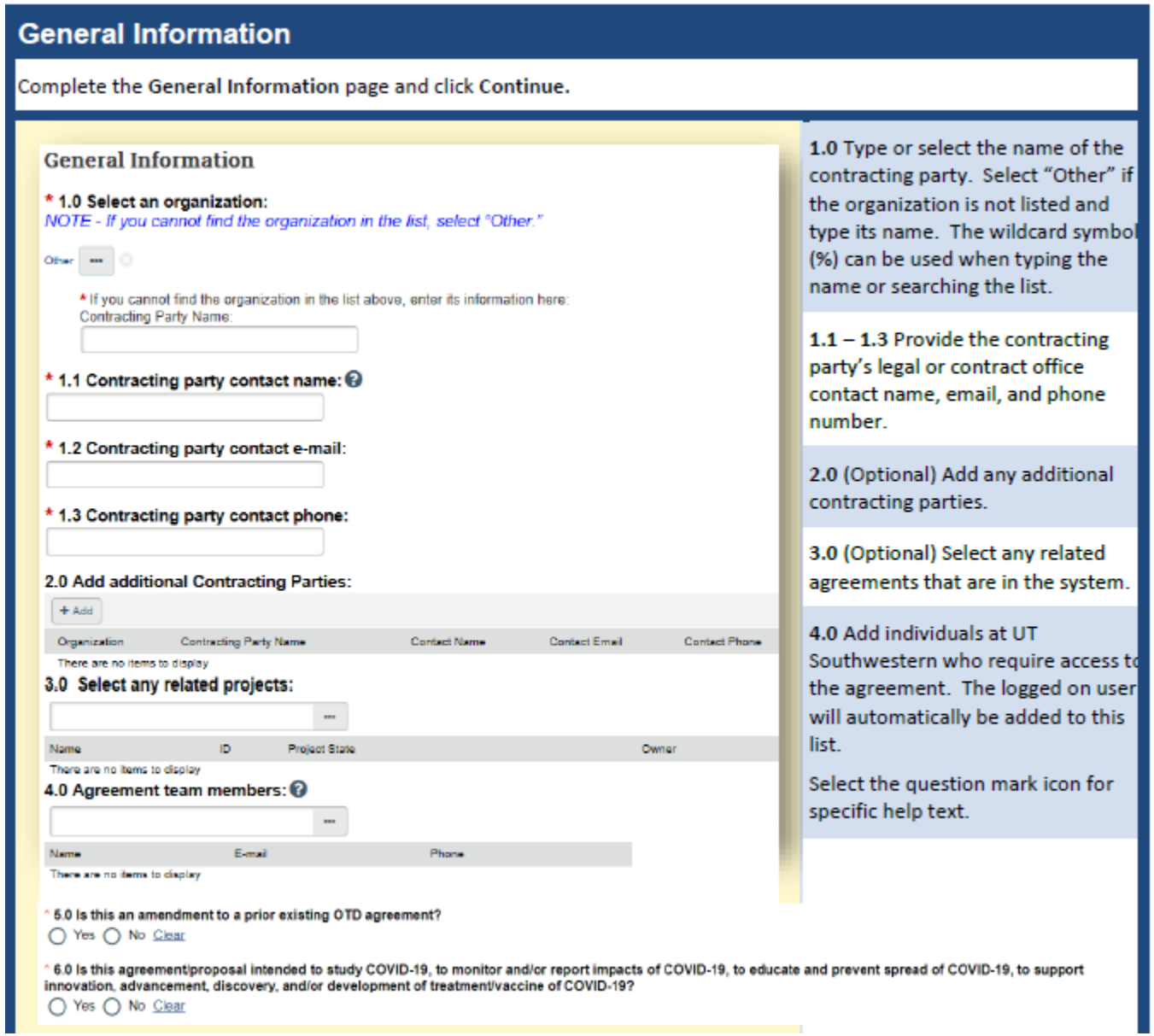
TIPS FOR SUBMITTING DUA

6.0 Supporting documents: Upload list of data points. If limited data set, be sure to include dates or five-digit zip code or other geographic subdivision (except street address).

7.0 Description: **Question to answer in this section:**

- If you are given an agreement by organization, can we use UTSW agreement template instead?



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TIPS FOR SUBMITTING DUA

1.1: The contracting party should be the legal or contract office at the organization. Not having this information may cause a significant delay.

5.0 If you need to amend a prior agreement answer "Yes".

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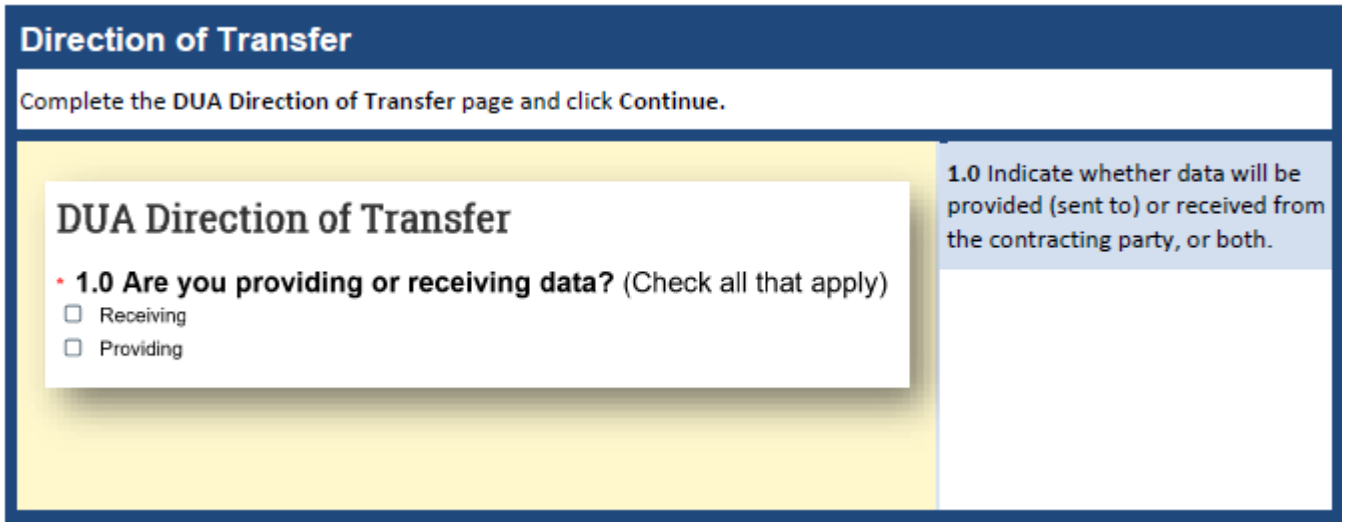
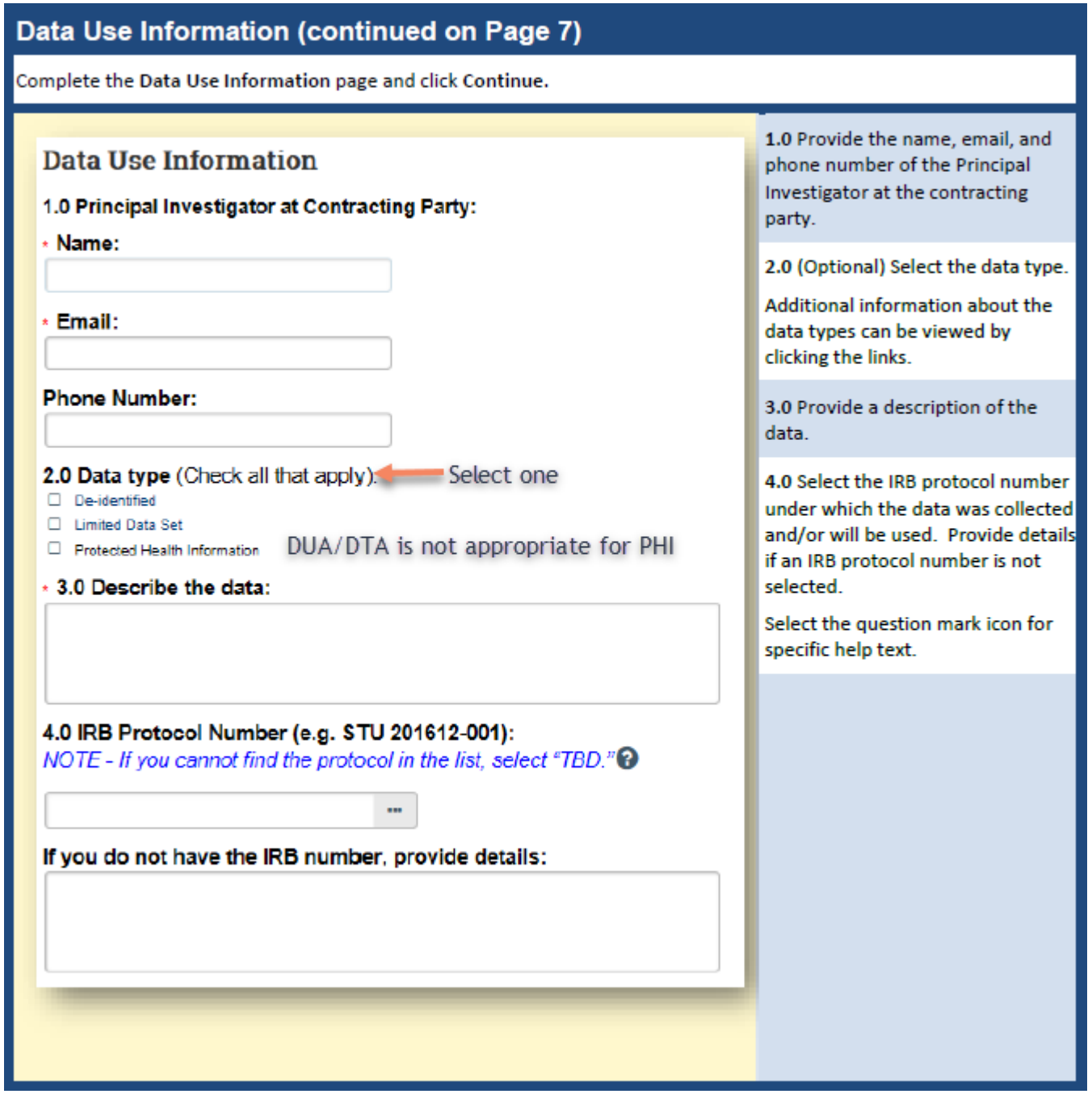
TIPS FOR SUBMITTING DUA



Receiving: Office of Technology Development (OTD). Agreements are assigned to OTD Department Liaisons. Contact Us: Technology Development - UT Southwestern, Dallas, Texas

Providing: HRPP

Receiving and Providing: HRPP



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TIPS FOR SUBMITTING DUA

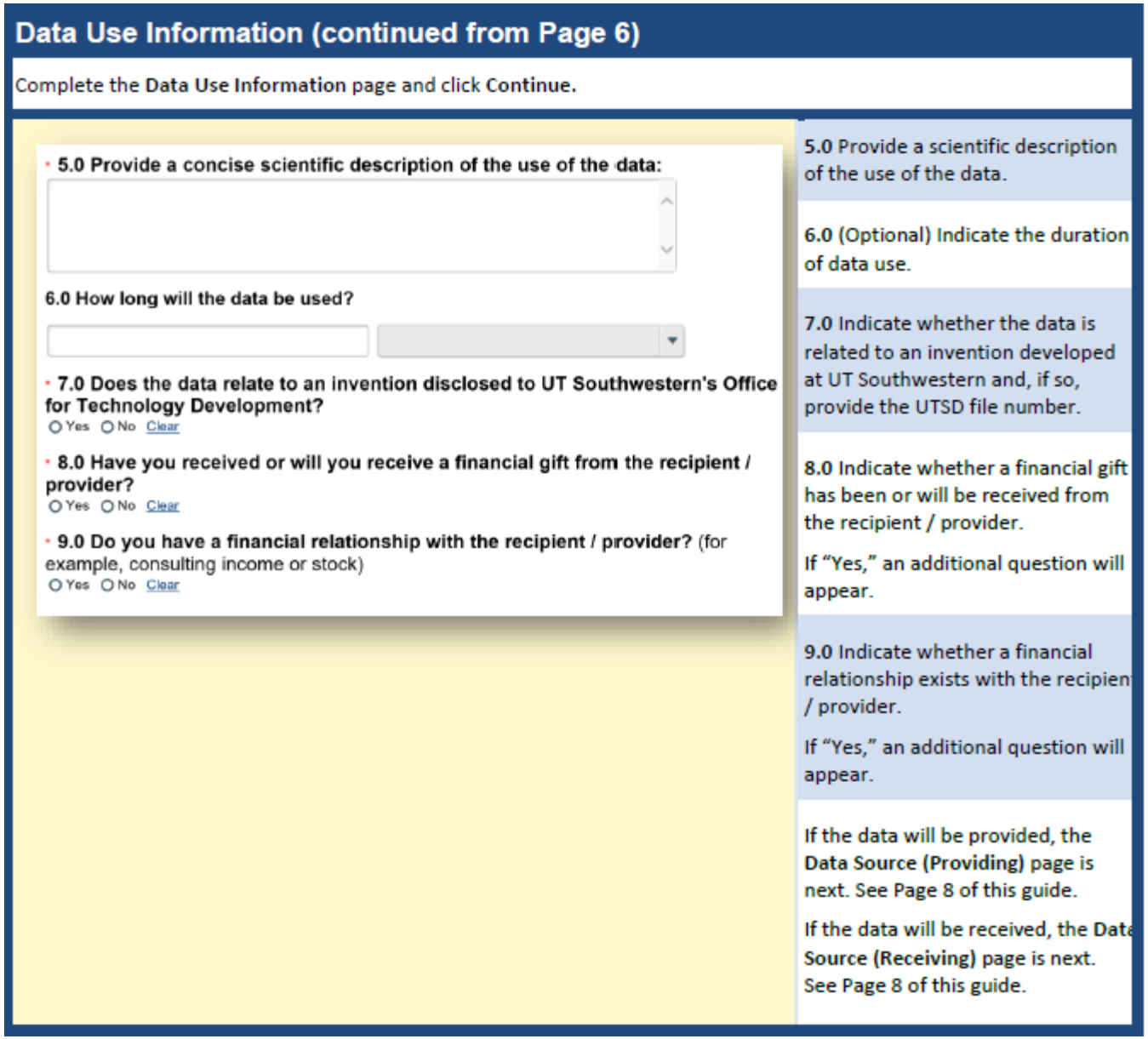
1.0 Name of PI at Contracting Party: Provide credentials

2.0 Data Type (Select one):

- De-identified: Not required for not-for-profit institution located in the United States
- Limited Data Set
- "Protected Health Information" – **DO NOT USE. See Transfer of DUA/DTA Decision Tree.**

3.0 Describe the data:
If you uploaded the document, type, "Refer to the list of data points uploaded in the Agreements Upload section, 6.0 Supporting documents."

4.0 IRB Protocol Number:
This is required so that the IRB can review the protocol, consent form, and smartform.



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TIPS FOR SUBMITTING DUA

5.0 Explain how the PI at the other organization will use the data.

6.0 How long will the data be used? The number of years that the data will be used is needed for the agreement.

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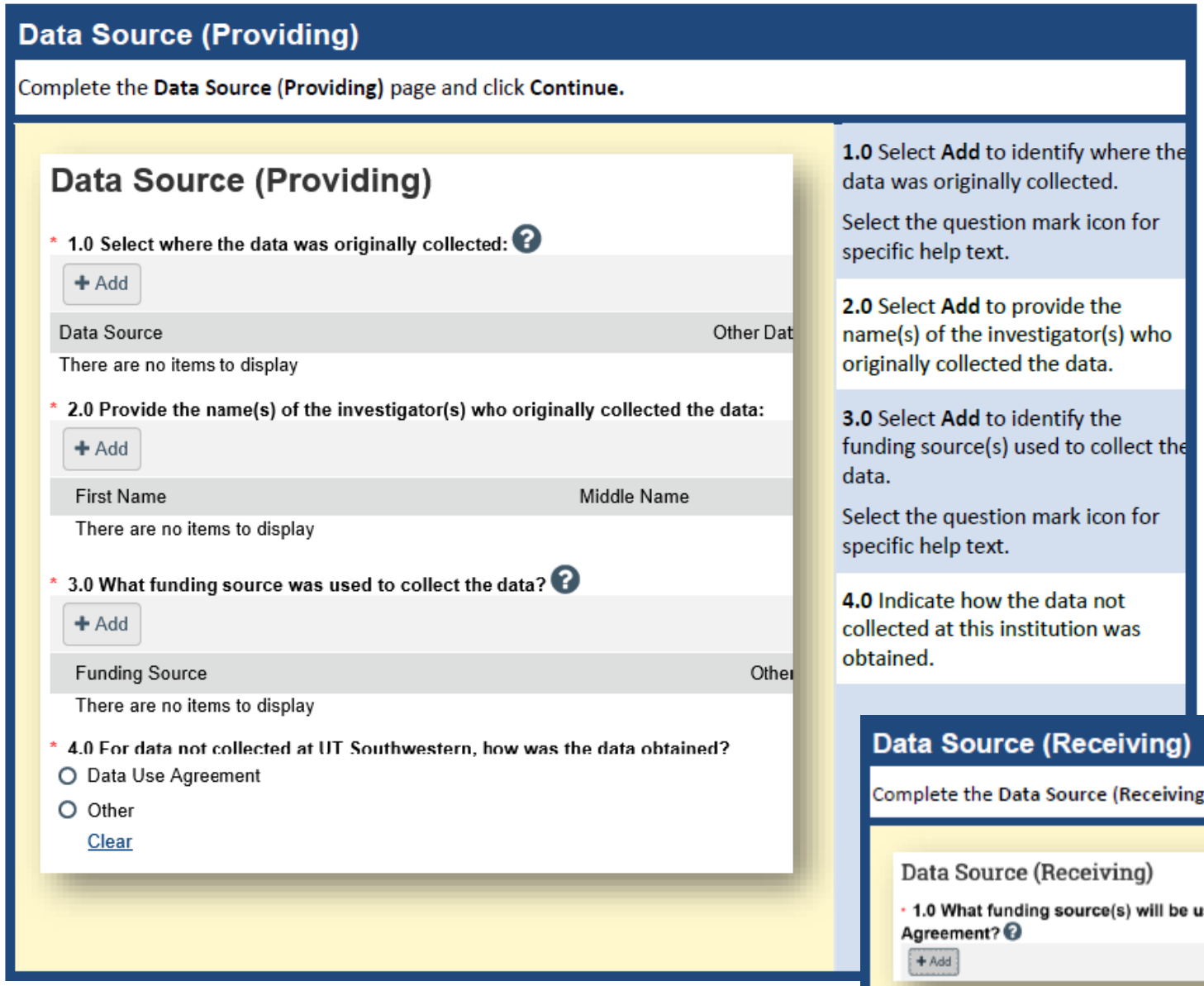
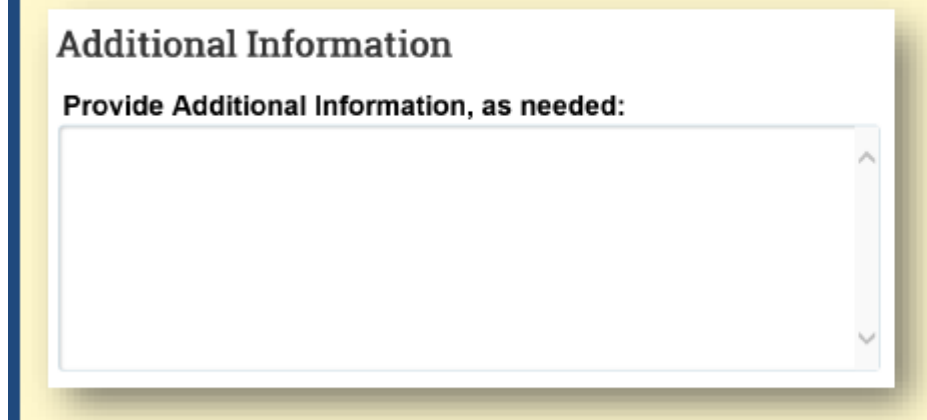
TIPS FOR SUBMITTING DUA

1.0 List the source of the data. This is important, particularly with Parkland, as they must be named on the agreement if they are a source.



Additional Information

Complete the **Additional Information** page and click **Finish.**

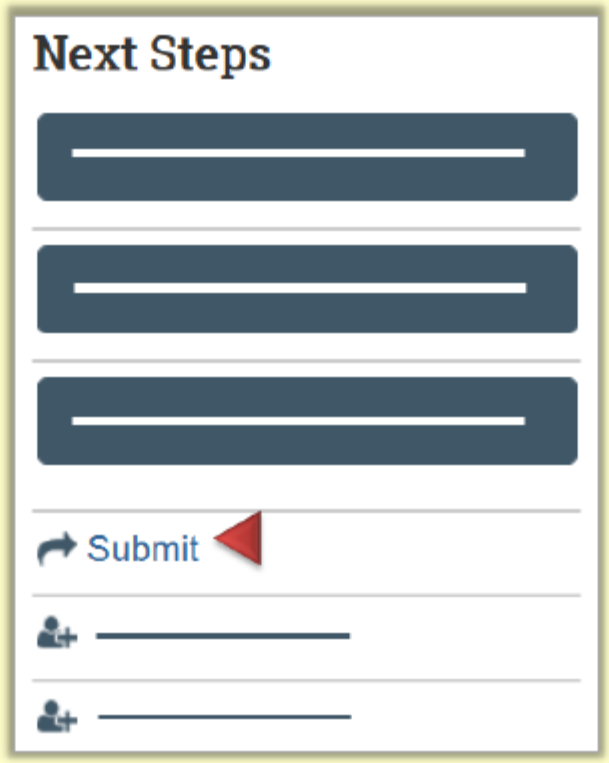


1.0 (Optional) Provide any comments about the agreement.

After clicking **Finish**, the Agreement Workspace will appear.

Submit the Agreement

From the Agreement Workspace, click the **Submit** button on the left side of the screen.



What is the workflow?

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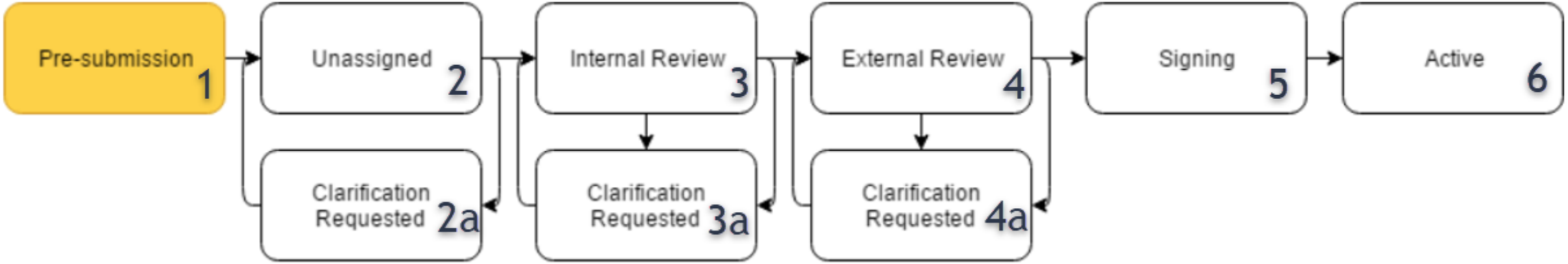

Questions

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Thank You!

- **We'd love to hear your feedback.** We invite you to provide your evaluation of Research Matters and of the Human Research Protection Program.

- Visit: https://ais.swmed.edu/redcap/surveys/?s=3PRJFCFJJW