
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

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

What is Data/Biospecimen Sharing?



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.

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



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 conducted in whole or in part by NIH that results in the generation of scientific data.

Protocol Considerations

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?



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

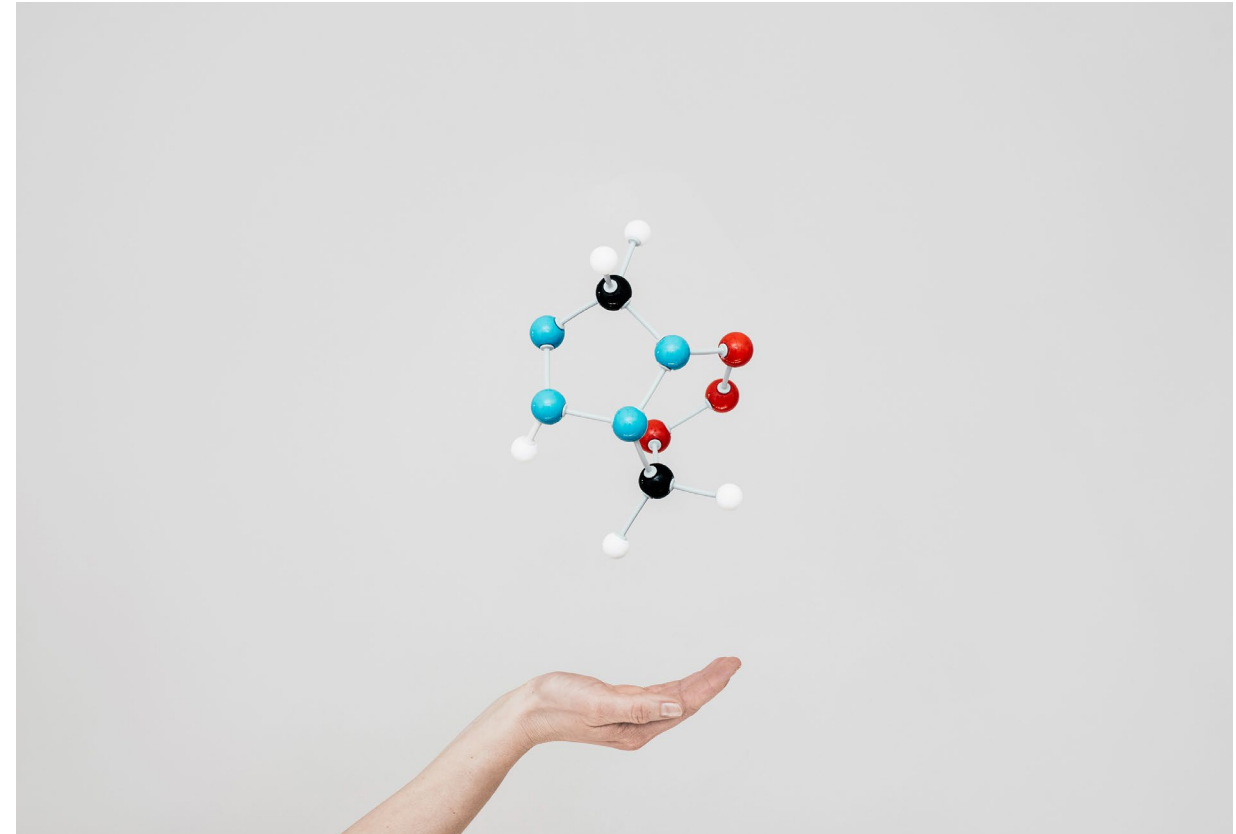
The data or biospecimen will be shared with one or more elements of PII and/or PHI

Why are the Materials Being Shared?

- 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?

- 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?

- 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?

- 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?

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?



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

- 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



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

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

Result	Plan	Information to Participant
<ul style="list-style-type: none">• Information that is critical to the management of a participant's health in the immediate/near future.	<ul style="list-style-type: none">• Immediately return information to the participant, and/or the participant's care provider if the participant agrees, so the participant can obtain appropriate healthcare.	<ul style="list-style-type: none">• 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

Result

- A known implication about health or risk, and are clinically actionable but not emergent (e.g., not severe or particularly time sensitive).

Plan

- Return these results if feasible and participant agrees. Considerations:
 - resources to return results
 - how you can facilitate next steps for participant's healthcare

Information to Participant

- 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

Result

- Known implication about health or risk but are not clearly clinically actionable.

Plan

- 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

Information to Participant

- 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

Result

- Results that do not have a known implication for health or risk.

Plan

- 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

Information to Participant

- 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

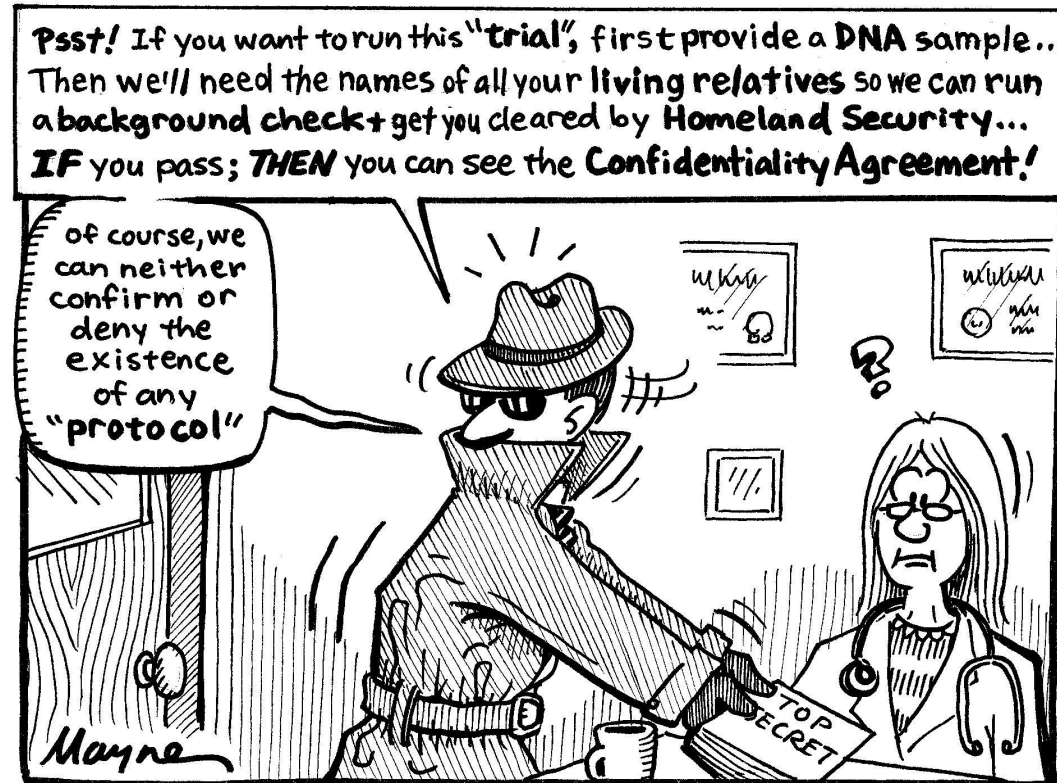
Consent for Sharing Not Obtained

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



DATA USE AGREEMENTS & MATERIALS TRANSFER AGREEMENTS

What is a Data Use Agreement (DUA)?

- 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

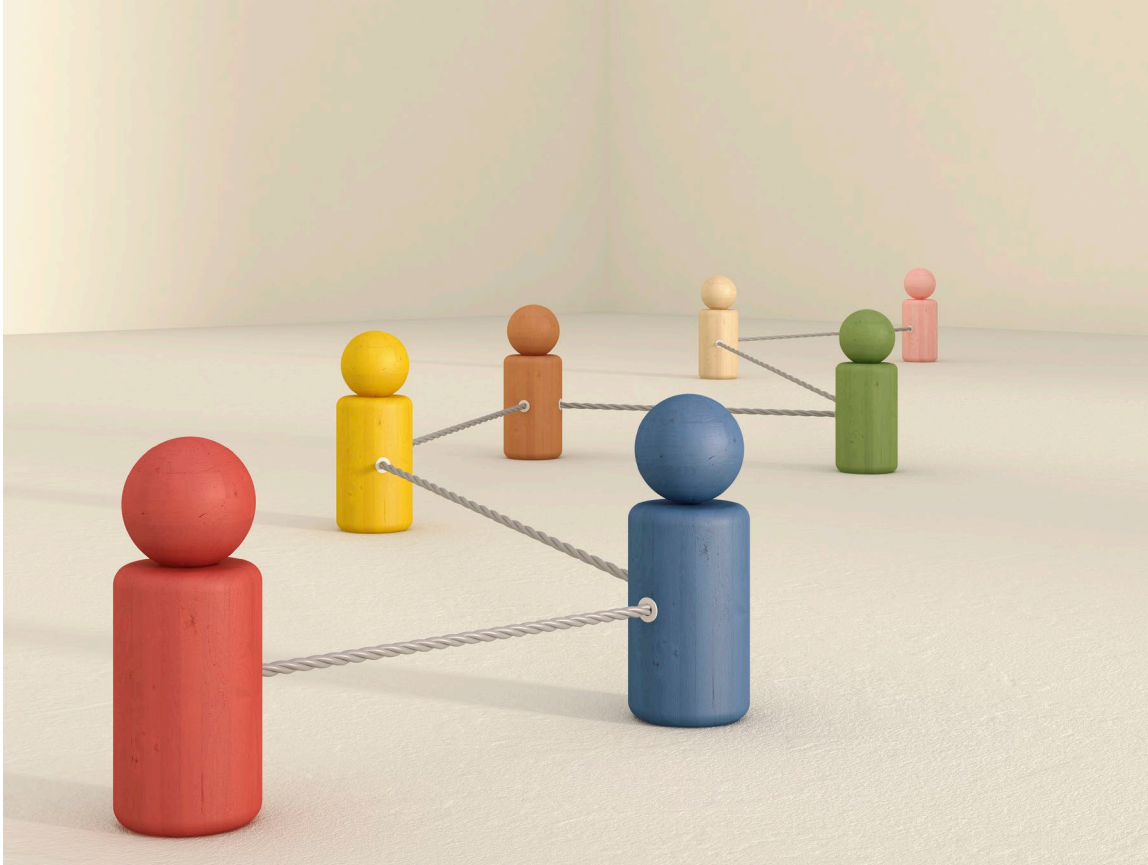
This Data Transfer Agreement (“**Agreement**”) is between:

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, [REDACTED] (“**Scientist**”):

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

[REDACTED] (“**Recipient**”), on behalf of its investigator, Dr. [REDACTED] (“**Investigator**”), for the following use: [REDACTED] (“**Research**”).

When is a DUA needed?



- 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)?

- 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”.





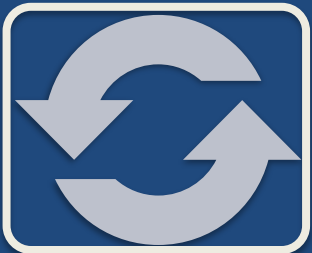
Protocol

- 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?

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

Create the Agreement

From My Inbox, click the **Create Agreement** button.

Create Agreement

All Agreements

Reports

Help Center

My Inbox

Filter ? ID

ID	Name

Agreement Upload

Complete the **Agreement Upload** page and click **Continue**.

Agreement Upload

* 1.0 Principal Investigator:

* 2.0 Entered by (Department Contact, Department Administrator, Study Coordinator, etc.):

* 3.0 If you have an agreement draft, upload it here. Otherwise, check the "UT Southwestern to generate first draft" box: ?

UT Southwestern to generate first draft? ☐

* 4.0 Provide a short name for the agreement: ?

* 5.0 Agreement type: ?

6.0 Supporting documents:

Name

There are no items to display

7.0 Description:

1.0 Type or select the Principal Investigator name.

2.0 Automatically populates with the logged on user. This user can submit the agreement on behalf of the PI.

3.0 If the contracting party provided a draft agreement, upload it here. Otherwise, select the checkbox.

Select the question mark icon for specific help text.

4.0 Provide a name for the agreement.

Select the question mark icon for specific help text.

5.0 Select the **Data Use Agreement** option.

Select the question mark icon for specific help text.

6.0 (Optional) Attach any supporting documents or correspondence with the Contracting Party or PI.

7.0 (Optional) Add descriptive information, as needed.

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?

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”.

General Information

Complete the General Information page and click Continue.

General Information

*** 1.0 Select an organization:**

NOTE - If you cannot find the organization in the list, select "Other."

Other:

* If you cannot find the organization in the list above, enter its information here:

Contracting Party Name:

*** 1.1 Contracting party contact name:**

*** 1.2 Contracting party contact e-mail:**

*** 1.3 Contracting party contact phone:**

2.0 Add additional Contracting Parties:

[+ Add](#)

Organization	Contracting Party Name	Contact Name	Contact Email	Contact Phone
There are no items to display				

There are no items to display

3.0 Select any related projects:

Name	ID	Project State	Owner
There are no items to display			

There are no items to display

4.0 Agreement team members:

Name	E-mail	Phone
There are no items to display		

There are no items to display

*** 5.0 Is this an amendment to a prior existing OTD agreement?**

☐ Yes ☐ No [Clear](#)

*** 6.0 Is this agreement/proposal intended to study COVID-19, to monitor and/or report impacts of COVID-19, to educate and prevent spread of COVID-19, to support innovation, advancement, discovery, and/or development of treatment/vaccine of COVID-19?**

☐ Yes ☐ No [Clear](#)

1.0 Type or select the name of the contracting party. Select "Other" if the organization is not listed and type its name. The wildcard symbol (%) can be used when typing the name or searching the list.

1.1 – 1.3 Provide the contracting party's legal or contract office contact name, email, and phone number.

2.0 (Optional) Add any additional contracting parties.

3.0 (Optional) Select any related agreements that are in the system.

4.0 Add individuals at UT Southwestern who require access to the agreement. The logged on user will automatically be added to this list.

Select the question mark icon for specific help text.

TIPS FOR SUBMITTING DUA

Direction of Transfer

Complete the DUA Direction of Transfer page and click Continue.

DUA Direction of Transfer

- **1.0 Are you providing or receiving data?** (Check all that apply)
 - ☐ Receiving
 - ☐ Providing

1.0 Indicate whether data will be provided (sent to) or received from the contracting party, or both.

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

Data Use Information (continued on Page 7)

Complete the Data Use Information page and click Continue.

Data Use Information

1.0 Principal Investigator at Contracting Party:

* Name:

* Email:

Phone Number:


2.0 Data type (Check all that apply): Select one

- ☐ De-identified
- ☐ Limited Data Set
- ☐ Protected Health Information

DUA/DTA is not appropriate for PHI

* 3.0 Describe the data:

4.0 IRB Protocol Number (e.g. STU 201612-001):

NOTE - If you cannot find the protocol in the list, select "TBD." 

If you do not have the IRB number, provide details:

1.0 Provide the name, email, and phone number of the Principal Investigator at the contracting party.

2.0 (Optional) Select the data type.

Additional information about the data types can be viewed by clicking the links.

3.0 Provide a description of the data.

4.0 Select the IRB protocol number under which the data was collected and/or will be used. Provide details if an IRB protocol number is not selected.

Select the question mark icon for specific help text.

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.

Data Use Information (continued from Page 6)

Complete the Data Use Information page and click Continue.

• **5.0 Provide a concise scientific description of the use of the data:**

6.0 How long will the data be used?

• **7.0 Does the data relate to an invention disclosed to UT Southwestern's Office for Technology Development?**

☐ Yes ☐ No [Clear](#)

• **8.0 Have you received or will you receive a financial gift from the recipient / provider?**

☐ Yes ☐ No [Clear](#)

• **9.0 Do you have a financial relationship with the recipient / provider? (for example, consulting income or stock)**

☐ Yes ☐ No [Clear](#)

5.0 Provide a scientific description of the use of the data.

6.0 (Optional) Indicate the duration of data use.

7.0 Indicate whether the data is related to an invention developed at UT Southwestern and, if so, provide the UTSD file number.

8.0 Indicate whether a financial gift has been or will be received from the recipient / provider.

If "Yes," an additional question will appear.

9.0 Indicate whether a financial relationship exists with the recipient / provider.

If "Yes," an additional question will appear.

If the data will be provided, the Data Source (Providing) page is next. See Page 8 of this guide.

If the data will be received, the Data Source (Receiving) page is next. See Page 8 of this guide.

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.

Data Source (Providing)

Complete the **Data Source (Providing)** page and click **Continue**.

Data Source (Providing)

* 1.0 Select where the data was originally collected: ?

+ Add

Data Source

Other Data

There are no items to display

* 2.0 Provide the name(s) of the investigator(s) who originally collected the data:

+ Add

First Name

Middle Name

There are no items to display

* 3.0 What funding source was used to collect the data? ?

+ Add

Funding Source

Other

There are no items to display

* 4.0 For data not collected at IIT Southwestern, how was the data obtained?

☐ Data Use Agreement

☐ Other

[Clear](#)

1.0 Select **Add** to identify where the data was originally collected.

Select the question mark icon for specific help text.

2.0 Select **Add** to provide the name(s) of the investigator(s) who originally collected the data.

3.0 Select **Add** to identify the funding source(s) used to collect the data.

Select the question mark icon for specific help text.

4.0 Indicate how the data not collected at this institution was obtained.

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.

Data Source (Receiving)

Complete the **Data Source (Receiving)** page and click **Continue**.

Data Source (Receiving)

* 1.0 What funding source(s) will be used to support the research under this Data Use Agreement? ?

+ Add

1.0 Select **Add** to identify the funding source(s) and chart(s) of account used to support the research on the received data.

Select the question mark icon for specific help text.

Additional Information

Complete the Additional Information page and click Finish.

Additional Information

Provide Additional Information, as needed:



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.

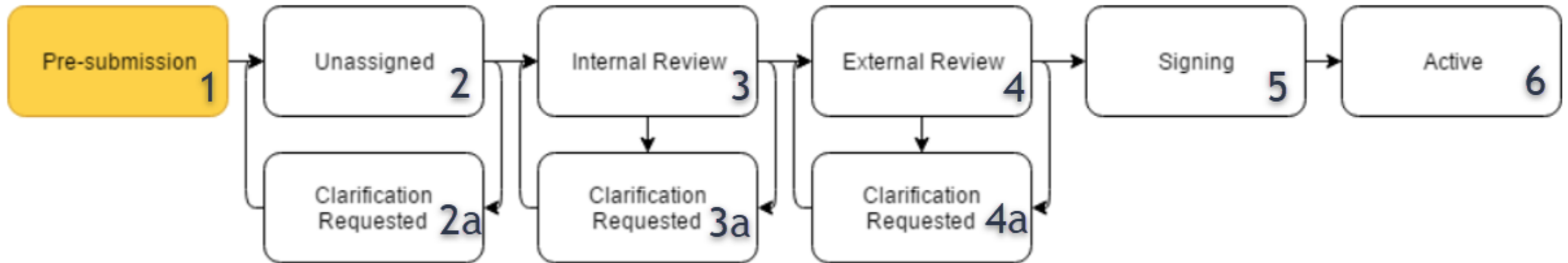
Next Steps

 **Submit** 





What is the workflow?





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>