UT Southwestern
Medical Center
Office of Research Regulatory Affairs

Secondary Use

Data and Materials Sharing

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Meyad Bird, BA, CIP, IRB Director
Kimberly A. Hawkins, BA, Business Analyst
IRB Office – Human Research Protection Program Department

Discussion Topics

- What is Data/Biospecimen Sharing?
- Regulatory Requirements
- Protocol and Consent Form Considerations
- eAgreement Requirements
- eIRB Requirements

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

Applicable Federal Regulations

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)

HIPAA Privacy Rule

- 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.

Protocol Considerations

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- What will be shared?
- Why are the materials (data/biospecimens) being shared?
- Who will the data/biospecimens 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

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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)

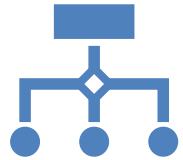
Coded Data/Biospecimen

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

Who will the Data/Biospecimens be Shared with?

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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?
  - 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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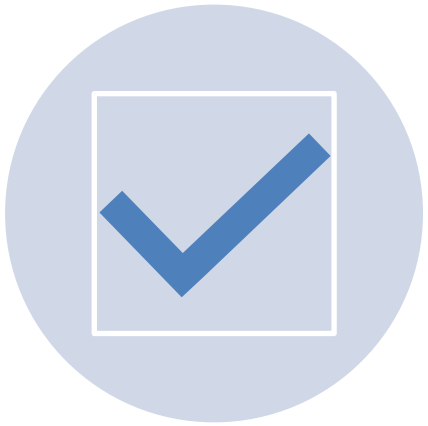

THE IRB MUST REVIEW THE DATA MANAGEMENT AND SHARING (DMS) PLAN TO ENSURE THAT THE PROTOCOL AND CONSENT FORM ARE CONSISTENT WITH THE PLAN.

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.

What are expectations at UTSW for sharing Human Data?

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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

Informed Consent/HIPAA Authorization

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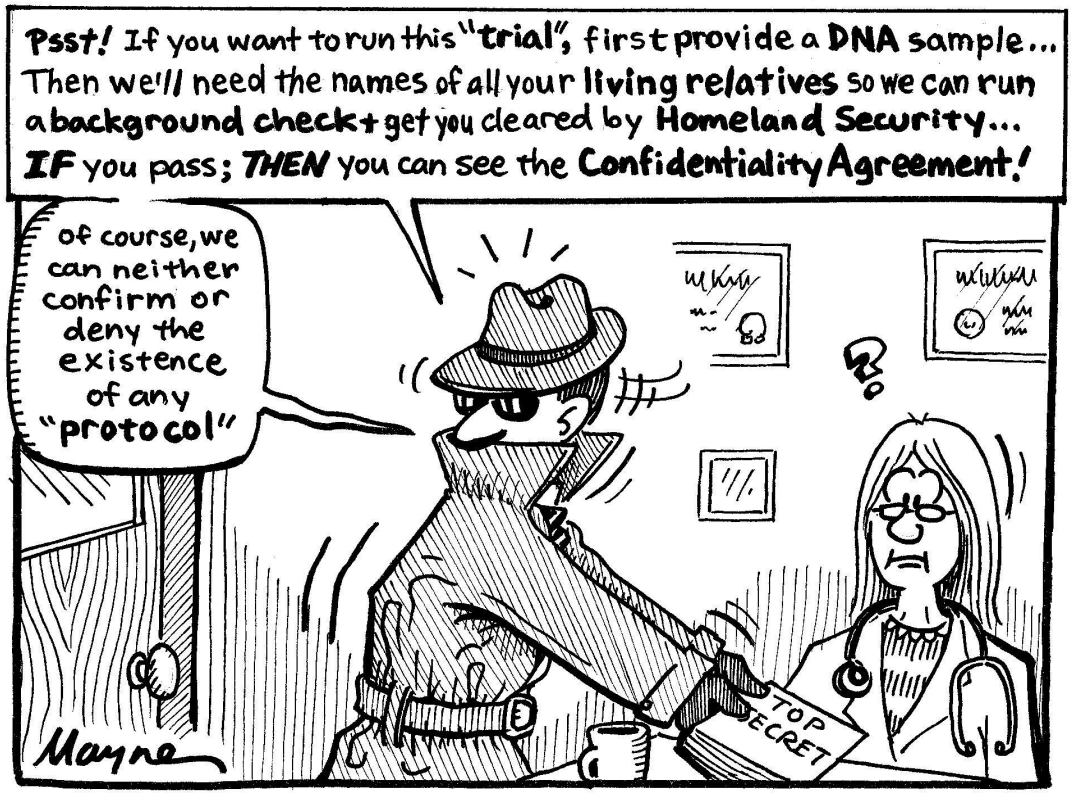
- Statement of sharing and purpose
- How confidentiality will be maintained
- Risks and benefits of sharing
- Security measures
- Returning clinically relevant results



AGREEMENT REQUIREMENTS

May I share data/specimens without additional permission or agreements?

NO

De-identified Data/Materials:

- HIPAA Authorization or a Data Use Agreement ("**DUA**") or an MMTA (if specimens will also be sent) is required unless there is another contract (e.g., CTA) that defines those terms.

Limited Data Set

(Dates [e.g., admission, discharge, service, dates of birth and if applicable, dates of death], five-digit zip code or any other geographic subdivision except street address)

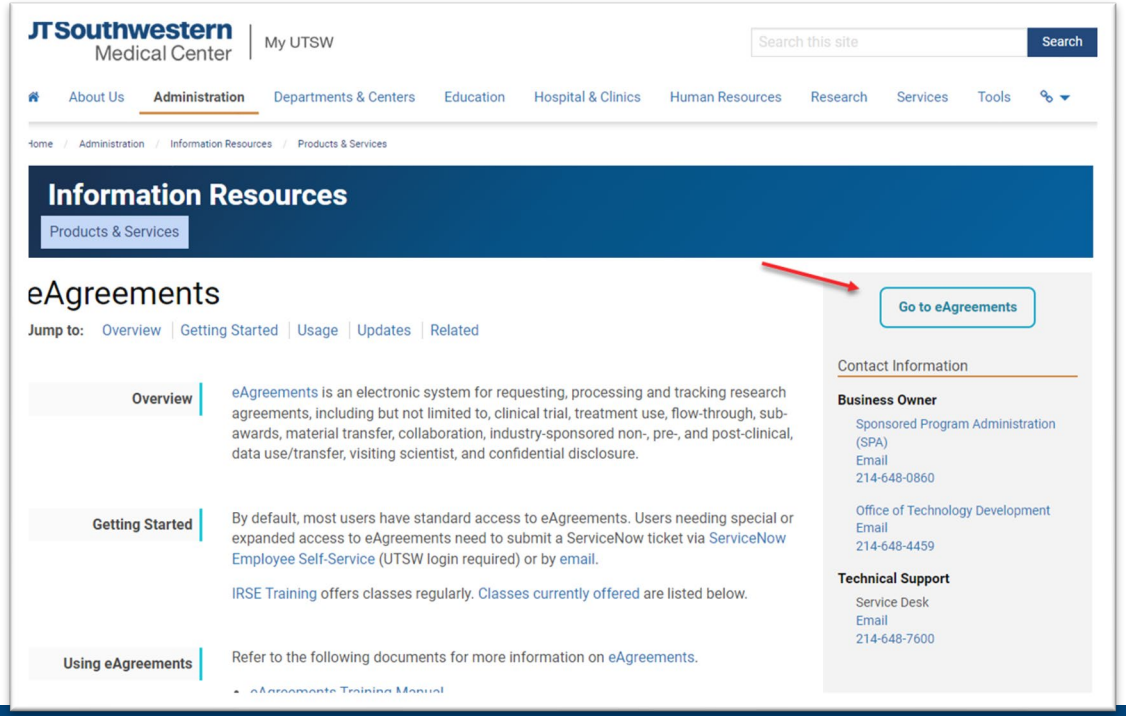
- HIPAA Authorization or a Data Use Agreement ("**DUA**") or an MMTA (if specimens will also be sent) is required unless there is another contract (e.g., CTA) that defines those terms.

Protected Health Information (PHI):

- A DUA/MMTA is not appropriate for data or materials that include PHI because the disclosure should be covered by the HIPAA Authorization language in the informed consent form or HIPAA Authorization waiver. If the external institution requires an agreement, they may provide one.

UTSW Uses eAgreements

This system is used to manage agreements including DUAs/MMTAs



eAgreements link:

https://eagreements.swmed.edu/eAgreements

Who Do I Contact about my Agreement?

- The HRPPD processes DUAs where investigators are ***providing*** or ***providing and receiving*** data ***AND*** the UTSW agreement template will be used. When the external organization requires use of their agreement, the DUA will be transferred to the Investigator's Department Liaison in the Office for Technology Development (OTD).

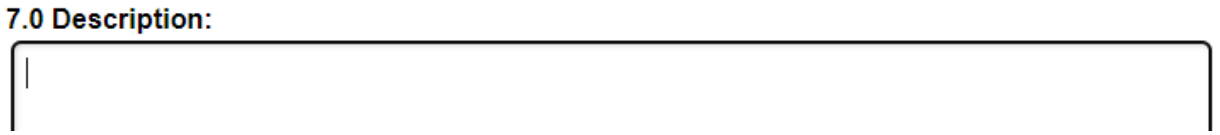
- OTD processes:
  - DUAs where human subject data will be ***received*** by investigators*
  - Collaborative Research Agreements (CRAs), Material Transfer Agreements (MTAs) and Sponsored Research Agreements (SRAs)*
  - *Confidential Disclosure Agreements (CDAs)*
  - *Visiting Scientist Agreements (VSAs)*

  *The HRPPD performs an Ancillary Review when these agreements involve human subject data and/or specimens.

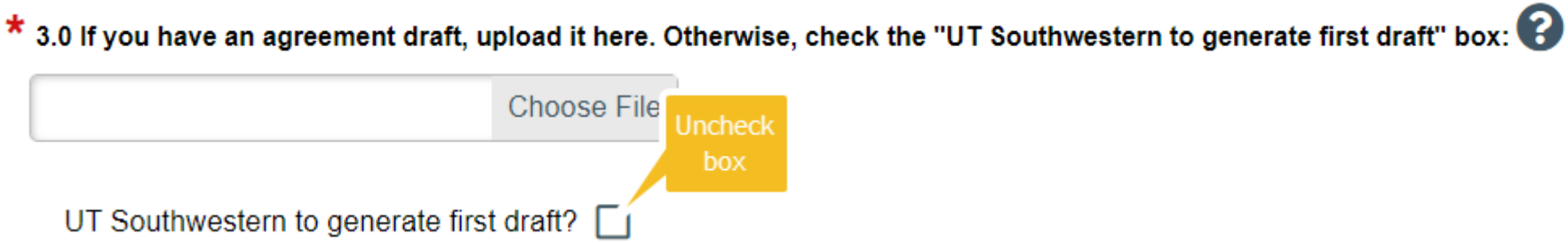
- Find the agreement you need through the Contracts and Agreements Pathfinder (CAP), a tool that UT Southwestern created that allows users to work through a flowchart to accurately identify the appropriate system and agreement type for their research. Pathfinder (CAP) will connect with eAgreements for ease of access to appropriate forms to initiate an agreement. Employees can only access Pathfinder (CAP) through the intranet.

eAgreements – Commonly Requested DUA Changes

- **Tab, "Agreement Upload"**
  - **3.0 Agreement Draft:**
    - If UTSW will ***provide*** the data/materials, the UTSW agreement template will be used unless a reason is given in Item 7.0:



    - If UTSW is receiving or receiving/providing data/materials, the external organization may provide their agreement template and it would be uploaded in Item 3.0.

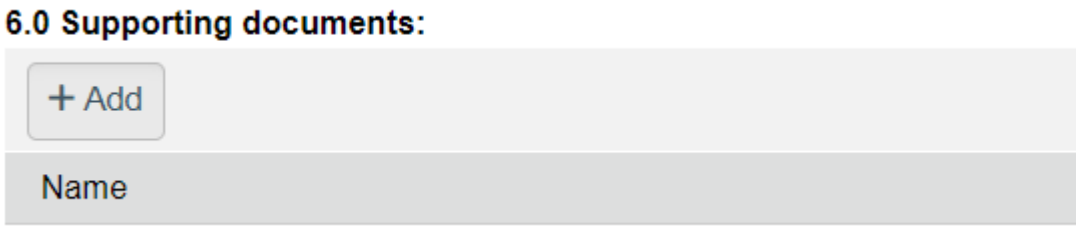


eAgreements – Commonly Requested DUA Changes, Continued

- **Tab, “Agreement Upload”**
  - **6.0 Supporting documents:** Upload the complete list of data points to be provided to the Contracting Party. *

    *The data points will be reviewed to confirm data type (de-identified, limited data set, protected health information) and will be included or summarized in the agreement.

  - **6.0 Supporting documents:** Studies ***Relying on an External IRB***: Submit the request to share data with an institution/entity to the External IRB in a modification and upload the approval letter in this section.

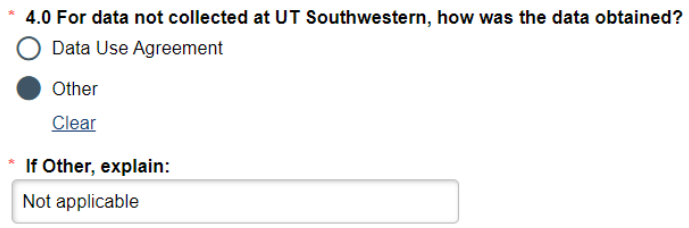


eAgreements – Commonly Requested DUA Changes, Continued

- **Tab, "UTSW DUA Data Use Information"**
  - **2.0 Data Type:** Although 2.0 says, "Select all that apply", select the most ***appropriate*** response instead:
    - **De-identified**: The data do not contain any of the 18 HIPAA Identifiers (names, telephone numbers, fax numbers, email addresses, social security numbers, medical record numbers, etc.).
    - **Limited Data Set**: HIPAA identifiers are limited to ***dates*** (e.g., admission, discharge, service, dates of birth and if applicable, death), ***five-digit zip codes***, and/or any other ***geographic subdivision*** except street address.
    - **Protected Health Information**: The data include the 18 HIPAA identifiers beyond that of a limited data set.
  - **4.0 IRB Protocol Number:** ***Note – This requirement applies to any agreement involving human subject data or specimens***
    - List the eIRB study number from/to which the data will be provided/received.
    - If your research does not qualify as research that needs to be submitted in eIRB, check to see if it qualifies as one of the following instead:
      - **Non-Human Research** (Y1 Form) – *Submit if ALL data/specimens in the research will be anonymous to investigators AND study is not FDA regulated*
      - **Non-Regulated Research** (Y2 Form) - *Submit for projects not intended as Research (Health surveillance, Routine Quality Improvement, Medical Quality Assurance, Program Evaluation, Academic Projects, Case Reports, etc.)*
      - Complete the appropriate form and submit it to HRPP@UTSouthwestern.edu. When you receive the Determination Letter in Outlook, upload it in the "Agreement Upload" tab, Item 6.0: Supporting Documents.

eAgreements – Commonly Requested DUA Changes, Continued

- **Tab, "UTSW DUA Data Use Information"**
  - **5.0 Concise scientific description of the use of the data:** Describe how UTSW and/or the external organization are going to use the data being exchanged. ***Note: Unless the external organization is conducting the same study that is being done at UTSW, this description will not match the purpose of the study in eIRB.***
    - List the external organization's study number and study title so it can be listed on the agreement.
  - **6.0 How long will the data be used?**
    - This will be used to determine the expiration of the agreement and may not be longer than 10 years. An amendment may be submitted to extend the term if needed.
- **Tab, "UTSW DUA Data Source Providing"**
  - **4.0 For data not collected at UT Southwestern, how was the data obtained:**
    - Because the data was collected from UTSW according to Item 1.0, "Select where the data was originally collected", select "Other" and type "Not applicable".



eIRB Requirements

Data and Materials sharing require disclosure in eIRB

eIRB link:

https://eresearch.swmed.edu/eIRB

eIRB Requirements – De-identified Data Set with or without Materials

A modification is not required to disclose that de-identified data/materials will be shared but it must be added to the study in eIRB by the HRPP Ancillary Reviewer.

Complete the following statement and send it to the HRPP Ancillary Reviewer when they contact you so that they can administratively add it to the study for you in eIRB Smartform Item 24.1.1a (eIRB Lite), Item 63.3 (Legacy *[Studies starting with "Study" or "STU " instead of "STU-"]* - Full Board, Expedited, Relying on an External IRB), or Item 17.5 (Legacy - Exempt).

[A de-identified data set ***or*** A de-identified data set with materials ***or*** De-identified Materials] will be [provided to ***or*** **received from** ***or*** **provided to and received from**] [person at organization] under [Agreement #]. Include if data will be shared: The data will be made **viewable** and/or **transferred** by [explain how the data will be transferred (e.g., REDCap, encrypted, password-protected Excel spreadsheet, etc.)].

eIRB Requirements – Limited Data Set with or without Materials

Complete the following statement and ***modify*** eIRB Smartform Item 24.1.1a (eIRB Lite), Item 63.3 (Legacy *[Studies starting with "Study" or "STU " instead of "STU-"]* - Full Board, Expedited, Relying on an External IRB), or Item 17.5 (Legacy - Exempt).

[A limited data set ***or*** A limited data set with materials] will be [provided to ***or*** **received from** ***or*** **provided to and received from**] [person at organization] under [Agreement #]. Include if data will be shared: The data will be made **viewable** and/or **transferred** by [explain how the data will be transferred (e.g., REDCap, encrypted, password-protected Excel spreadsheet, etc.)].

eIRB Smartform Item 24.0

24.0 Data and Specimens

* **24.1 Will data/specimens be shipped to other facilities?** *Please note that shipping specimens offsite may require personnel to be DOT/IATA certified. Please call SBC at 214-648-2250 for more information. A Material Transfer Agreement may be required. The MTA is submitted in eAgreements (Link to eAgreements)*

● Yes ○ No Clear

* **24.1.1 Please indicate the name(s) of the facilities receiving the data/specimens:**

☐ NIH – dbGaP - Refer to dbGaP submission guidance for additional information

☐ NIH – NICHD DASH - Refer to NICHD DASH submission guidance for additional information

☑ Other

* **24.1.1a If other, please explain:**

* **24.1.2 Please indicate how the data/specimens will be labeled or identified prior to shipping:** *(select all that apply)*

☐ Anonymous – No identifying information will be connected to the data/specimens

☑ Coded – Data/specimens will be provided with a code and all direct identifiers (name, MRN, etc.) will be removed (local study team will retain the key to the code)

☐ Identifiable – Data/specimens will be provided with direct identifiers (name, medical record number, etc.)

☐ Other

* **24.2 Will the collected biological specimen(s) undergo genetic testing?**

○ Yes

● No genetic identification, gene mapping, genomic analysis, or DNA screening will occur.

Clear

Exit Save Continue

eIRB Smartform Item 63.3 (Legacy, Full Board, Expedited, Relying on an External IRB)

* 63.3 If coded or identified data will be released outside of UTSW or its affiliated hospitals, please specify the persons/agencies to whom the information will be released. Please also indicate the precautions that will be taken to assure that confidentiality will be maintained during transmission of the data:

eIRB Smartform Item 17.5 (Legacy, Exempt)

* 17.5 Describe the procedures to maintain confidentiality:

eIRB Requirements – Protected Health Information

- **Participants must reconsent and authorize the transfer:** The HIPAA Authorization needs to include the organization in the list to receive PHI as part of the study:

How will your PHI be shared?
Because this is a research study, we will be unable to keep your PHI completely confidential. We may share your health information with people and groups involved in overseeing this research study including:

- the Sponsor, [name the company], funding the study. The sponsor includes any people, entities, groups or companies working for or with the sponsor or owned by the sponsor. The sponsor will receive written reports about your participation in the research. The sponsor may look at your health information to assure the quality of the information used in the research.
- the company [name the company] that makes the study drug/device.
- the following collaborators at other institutions that are involved with the study: [insert name and institution – these are collaborators at institutions not affiliated with UTSW IRB]

Consent and HIPAA Authorization Forms

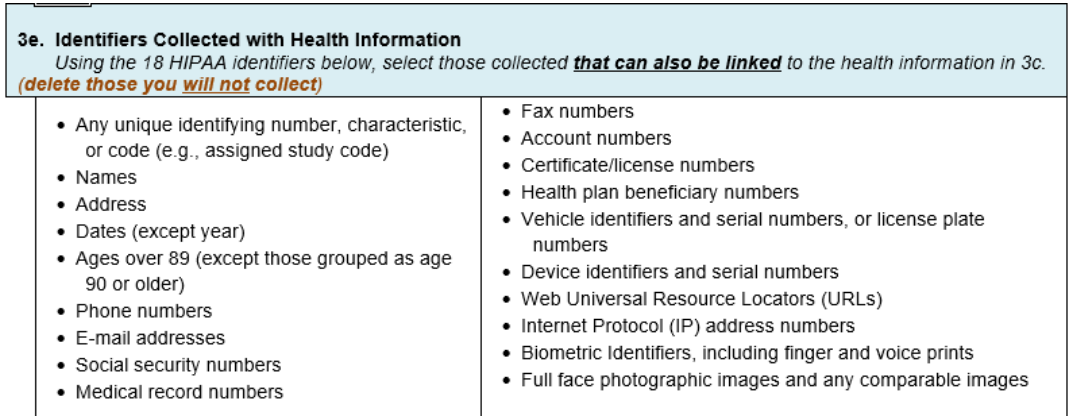
OR (continued on next page)

eIRB Requirements – Protected Health Information, Continued

Or

The IRB must waive the disclosure in the HIPAA Authorization Waiver/Alteration (Form H):

- **Item 3e:** HIPAA Waiver needs to allow for ***collection*** of PHI

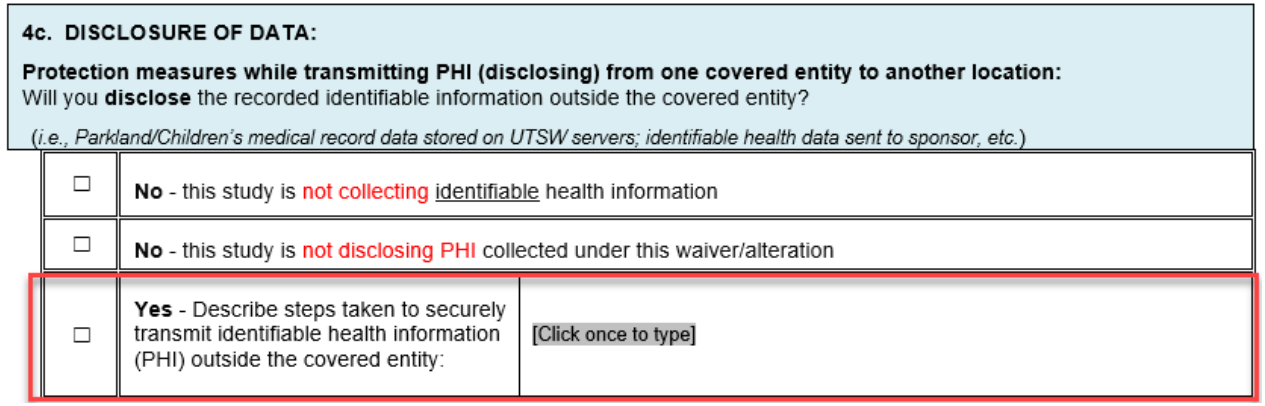


3e. Identifiers Collected with Health Information

*Using the 18 HIPAA identifiers below, select those collected **that can also be linked** to the health information in 3c.*
*(**delete those you will not collect**)*

- Any unique identifying number, characteristic, or code (e.g., assigned study code)
- Names
- Address
- Dates (except year)
- Ages over 89 (except those grouped as age 90 or older)
- Phone numbers
- E-mail addresses
- Social security numbers
- Medical record numbers
- Fax numbers
- Account numbers
- Certificate/license numbers
- Health plan beneficiary numbers
- Vehicle identifiers and serial numbers, or license plate numbers
- Device identifiers and serial numbers
- Web Universal Resource Locators (URLs)
- Internet Protocol (IP) address numbers
- Biometric Identifiers, including finger and voice prints
- Full face photographic images and any comparable images

- **Item 4.c:** HIPAA Waiver needs to allow for ***transfer*** of PHI:



4c. DISCLOSURE OF DATA:

Protection measures while transmitting PHI (disclosing) from one covered entity to another location:
Will you **disclose** the recorded identifiable information outside the covered entity?

(i.e., Parkland/Children's medical record data stored on UTSW servers; identifiable health data sent to sponsor, etc.)

☐	**No** - this study is not collecting identifiable health information	
☐	**No** - this study is not disclosing PHI collected under this waiver/alteration	
☐	**Yes** - Describe steps taken to securely transmit identifiable health information (PHI) outside the covered entity:	[Click once to type]

And (continued on next page)

eIRB Requirements – Protected Health Information, Continued

And

Complete the following statement and ***modify*** eIRB Smartform Item 24.1.1a or Item 63.3 (Legacy - Full Board, Expedited, Relying on an External IRB), or Item 17.5 (if Legacy - Exempt) to include one of the following statements:

> [Identifiable data ***or*** Identifiable data with materials ***or*** Identifiable Materials] will be [**provided to** ***or*** **received from** ***or*** **provided to and received from**] [person at organization] under [Agreement #]. Include if data will be shared: The data will be made **viewable** and/or **transferred** by [explain how the data will be transferred (e.g., REDCap, encrypted, password-protected Excel spreadsheet, etc.)].

eIRB Requirements – Studies Relying on an External IRB

- ***External IRB Modification:*** Submit a modification to the External IRB to request to provide to or receive data from an external organization.

- ***UTSW eIRB Modification:***
  - If the data request is approved by the External IRB, submit a modification to eIRB with the approval letter.

  - ***Complete*** the following statement and ***modify*** eIRB Smartform Item 24.1.1a, Item 63.3 (Legacy - Full Board, Expedited, Relying on an External IRB), or Item 17.5 (if Legacy - Exempt):

De-identified or Limited Data Set and/or Materials: *(Fill in the blanks)*

[A de-identified or limited data set ***or*** A de-identified or limited data set with materials ***or*** De-identified Materials] will be [provided to ***or*** **received from** ***or*** **provided to and received from**] [person at organization] under [Agreement #]. Include if data will be shared: The data will be made **viewable** and/or **transferred** by [explain how the data will be transferred (e.g., REDCap, encrypted, password-protected Excel spreadsheet, etc.)].

Identifiable Data and/or Materials: *(Fill in the blanks)*

[Identifiable data ***or*** Identifiable data with materials ***or*** Identifiable Materials] will be [**provided to** ***or*** **received from** ***or*** **provided to and received from**] [person at organization] under [Agreement #]. Include if data will be shared: The data will be made **viewable** and/or **transferred** by [explain how the data will be transferred (e.g., REDCap, encrypted, password-protected Excel spreadsheet, etc.)].

Questions?

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