

---

Research Matters  
Hosted by UT Southwestern's  
Human Research Protection Program

January 16, 2024



If you have any questions,  
please type them in the Q&A.



Sessions are recorded.  
Recording and documents will  
be posted to the Research  
Matters website, under [Training  
and Resources](#).



Attendance certificates will be  
sent to those who logged in  
with a valid email address  
(signed in and joined through  
Teams).

If you do not receive a  
certificate, email  
[HRPP@UTSouthwestern.edu](mailto:HRPP@UTSouthwestern.edu)



We want to hear from you!  
Provide feedback by visiting:



- **HRPP Department Updates**
  - **Institutional Review Board (IRB) Office**, *Meyad Bird, Director of Institution Review Board*
- **“Sponsor Investigators: Plan for your Monitoring Budget”** presented by *Manali Thakkar, MS, CHRC*
- **“Adding UTSW Affiliates to Studies”** presented by *Stephanie Francisco, BS, CIP*
- **Open Q&A Session**

# IRB Updates

January 2024

# Clinical Trial Modification IRB Holds



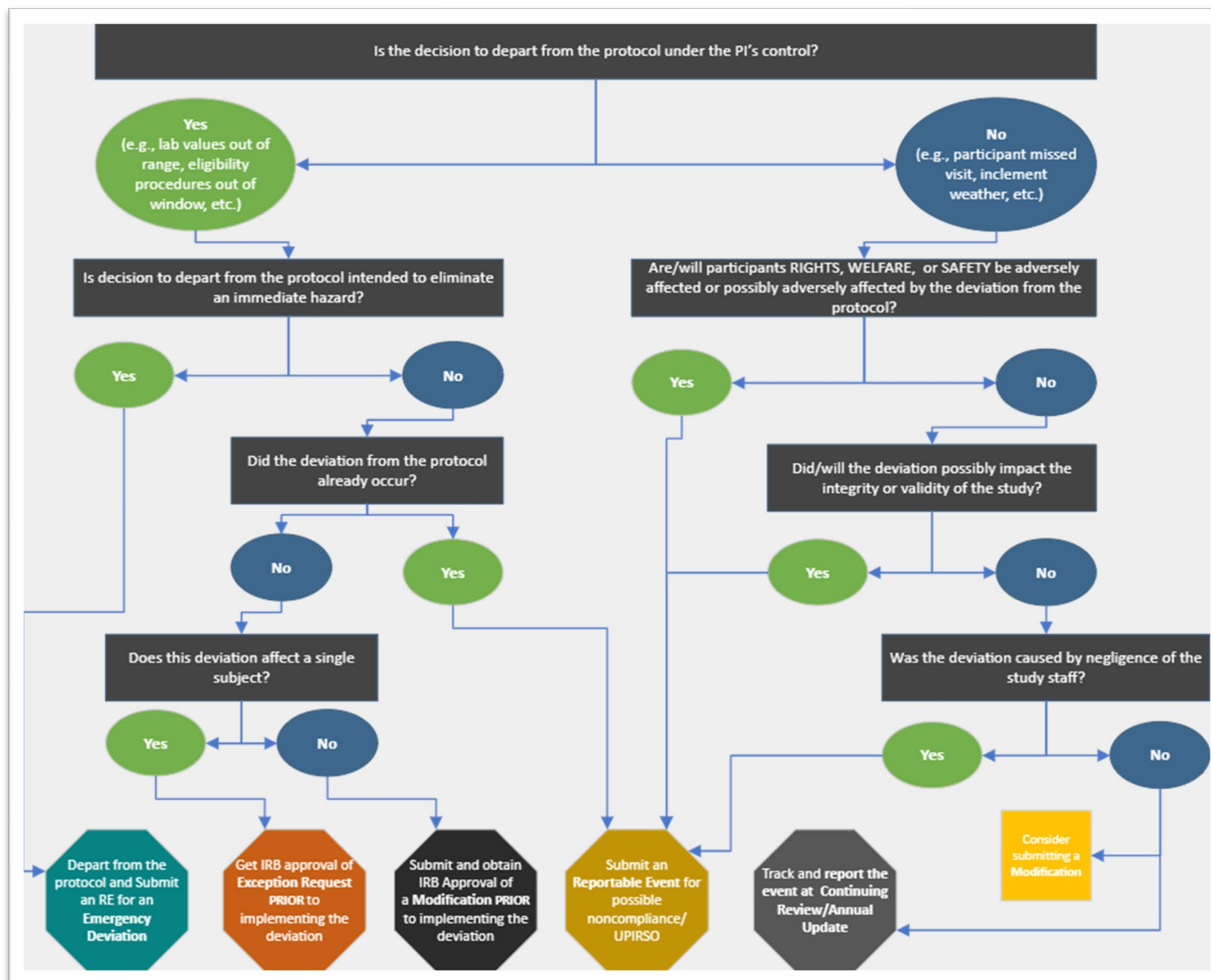
**PURPOSE:** of this update to allow for changes to the Coverage Analysis (CA) to be made where necessary to studies in which we are the IRB of record and when we are not the IRB of record (Reliance Studies)



**CHANGES IN PROCESS:** Modifications on studies which have a CA regardless of whether we are the reviewing IRB or an external IRB is responsible for the study will have approved documents held until SPA provides clearance that the CA has been approved or confirms that no changes are required.



**EXCEPTIONS:** Exceptions to this process include Modifications made due to safety reasons



# Materials Sharing with External Entities Tip Sheet

- I'd like to share Data and/or Materials with an External Entity
  - Provides you with helpful information on how to complete the eIRB application
  - Guidance for considerations on when participants need to be reconsented





## "I'd like to share Data and/or Materials with an External Entity"

*These are instructions to help you understand what the IRB requires to share data and/or materials.*

### De-identified Data:

- **eIRB Requirement:** De-identified data or materials sent or received do not need to be disclosed in smartform Items 24.1.1a or Items 63.3 or 46.6.1 (<sup>1</sup>Legacy) because data sharing does not involve HIPAA. A modification to the study to disclose that data and/or materials are being provided and/or received may be submitted but is not required.
- **eAgreements Requirement:** UTSW does not require a <sup>2</sup>DTA to provide de-identified data to a not-for-profit institution located in the United States. A DTA is required for *For-profit Entities in the US* and *International Entities*.

### Limited Data Set:

Select the correct template and submit modification to study in eIRB:

- <sup>3</sup>DUA: Smartform Item 24.1.1a or Item 63.3 (<sup>3</sup>Legacy):

#### Data to be Provided:

- A limited data set will be provided to [person] at [organization] under [DUA]. The data will be made **viewable** and/or **transferred** by [method (e.g., REDCap, encrypted, password-protected Excel spreadsheet, etc.)].

#### Data to be Received:

- A limited data set will be received from [person] at [organization] under [DUA]. The data will be made **viewable** and/or **transferred** by [method (e.g., REDCap, encrypted, password-protected Excel spreadsheet, etc.)].

- <sup>4</sup>MTA: Smartform Item 24.1.1a or Item 46.6.1 (Legacy):

#### Materials to be Provided:

- [MMTA]: [Description of what materials will be sent] will be sent to ([person] at [institution] or [commercial entity]).

#### Materials to be Received:

- [MMTA]: [Description of what materials will be received] will be received from ([person] at [institution] or [commercial entity]).

