UT Southwestern
Medical Center
Human Research Protection Program

UTSW ETHOS

System Transition and Key Features

November 19, 2024

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HRPP Administration

Agenda

- What is UTSW ETHOS
- System Transition
- Differences between eIRB and UTSW ETHOS
- Reliance Studies
- Navigation of UTSW ETHOS
  - Dashboard
  - Tabs
    - My Inbox
  - Recently Viewed
  - Pinned
- Submissions

System Transition Time

In preparation for the new system rollout, we want to provide you the following important information:

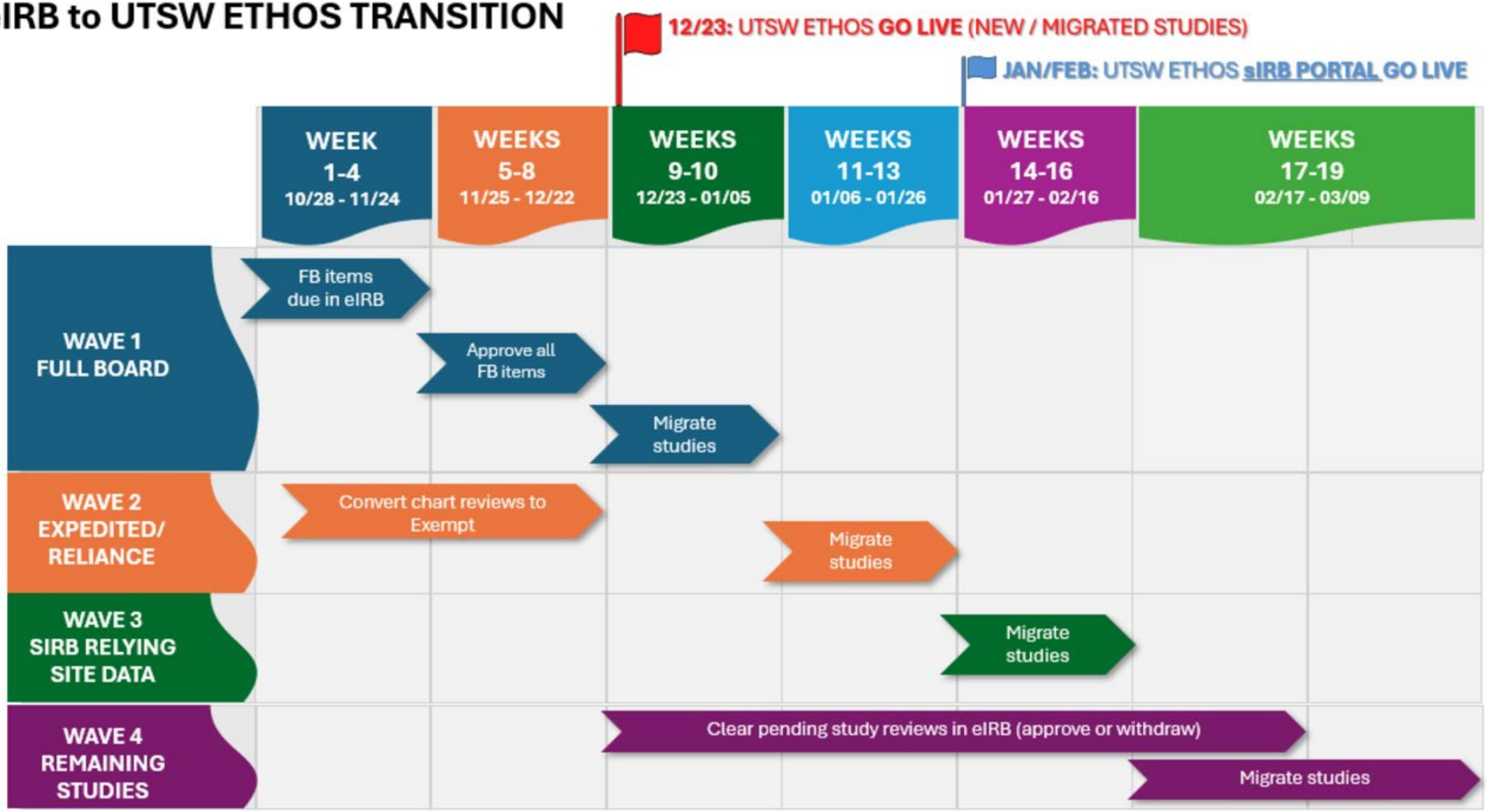
1. The IRB Office **will not** have ***any*** downtime during the migration and research will not be adversely affected. IRB reviews will continue to be accepted and reviewed during the phased study migration.
2. There will be limited functionality in the current eIRB system for *some* study types (details described in the next slide).
3. The new UTSW ETHOS will accept *all types of new study submissions* on **December 23, 2024**.
4. Studies expiring during the migration should submit continuing reviews prior to the transition. *The IRB Office will notify you if your studies are expiring to ensure the approval does not lapse*.
5. Please refer only to communication about the new **UTSW ETHOS** that has been generated by the UTSW Human Research Protection Program. This is necessary to ensure accurate information about the transition plan. (See UTSW ETHOS Updates)

Data Migration

- No full board *electronic* submissions (new studies, continuing reviews, and/or modifications) will be accepted in the current eIRB system from **November 24 – December 23, 2024**.**
  - This allows the IRB committees to complete all Full Board submissions by **December 18, 2024** (the final convened IRB meeting before system go-live).
  - Electronic submissions for Full Board review will need to be submitted into the old eIRB system by **November 24, 2024**.
- Study migration phases for activated studies are prioritized as follows (see next slide for eIRB to UTSW ETHOS Transition):
  - Full Board studies – open and not closed to enrollment
  - Full Board studies otherwise active
  - Expedited and External IRB (Reliance) studies
  - All other studies that were not active during initial migration phases
- The studies migration will be completed by the HRPP staff with the assistance of the Research and Academic Services (RAS) Office. There is no additional work expected from study teams to migrate active studies.

The IRB Office **will receive and review any urgent Full Board items during this time. While study teams will not be able to make *electronic* changes or submissions to existing Full Board studies at the start of December, the IRB Office staff will be able to make changes on your behalf, review, and approve any urgent submissions.

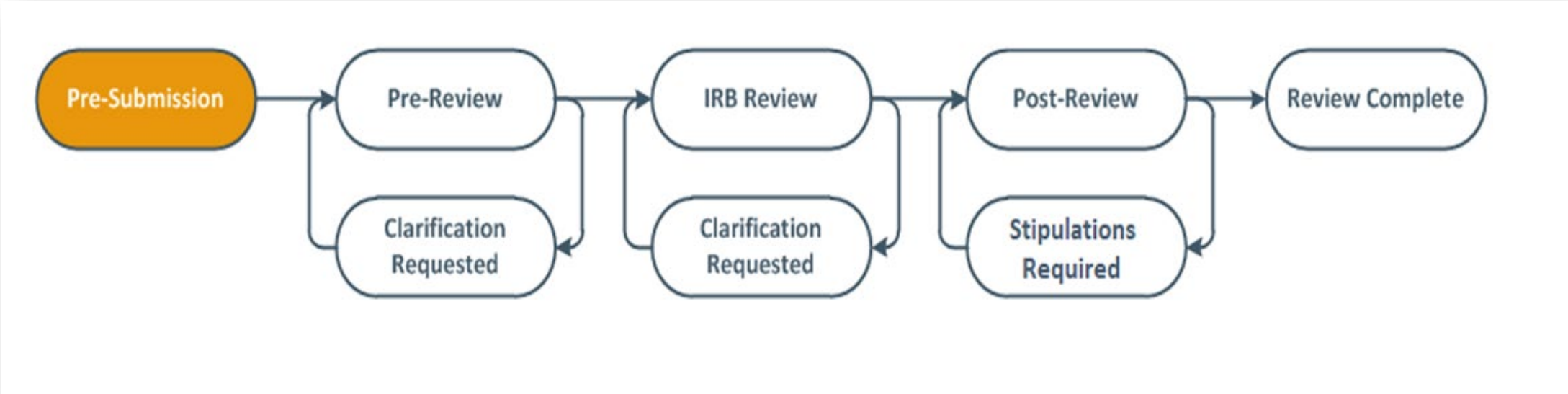
eIRB to UTSW ETHOS TRANSITION



UTSW ETHOS – Key Features

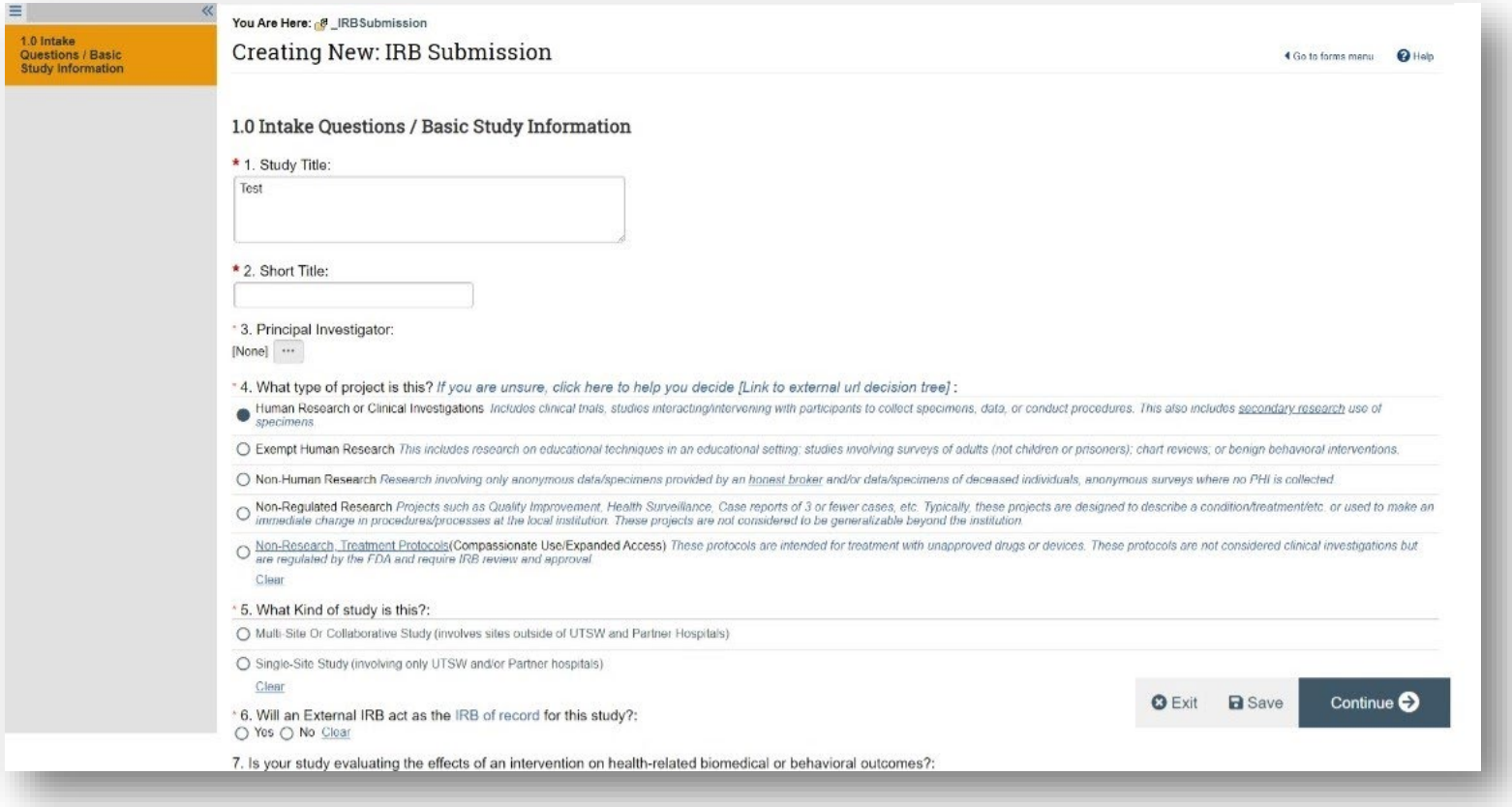
The following slides outlines some key features of the new UTSW ETHOS System:

The study workspace now has a workflow (flowchart). The workflow informs the user where the submission is at any given time throughout the review process up until approval. The flowchart is present for New Study Submissions, MODs, CRs / AUs / NSC, and Reportable Events.



UTSW ETHOS – Key Features

You will now be required to complete Intake Questions / Basic Study Information Page. The responses to this page will generate other sections to be completed within the study submission (section 1.0 of the UTSW ETHOS Smartform).



See UTSW ETHOS - Key Features for all Intake Questions.

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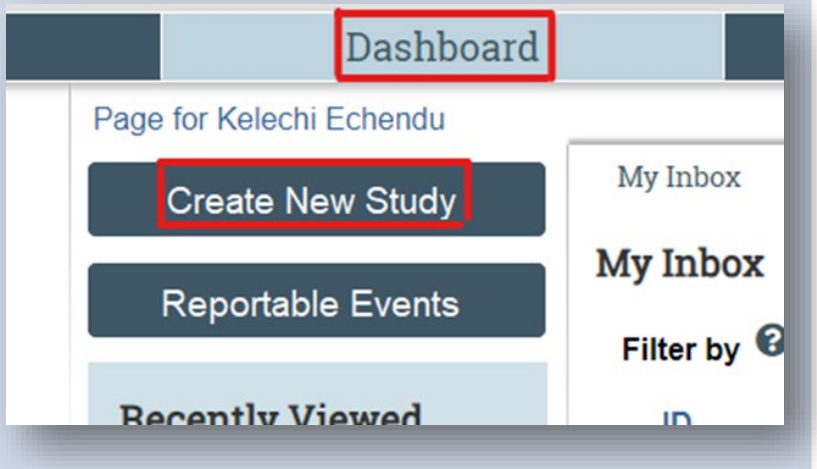
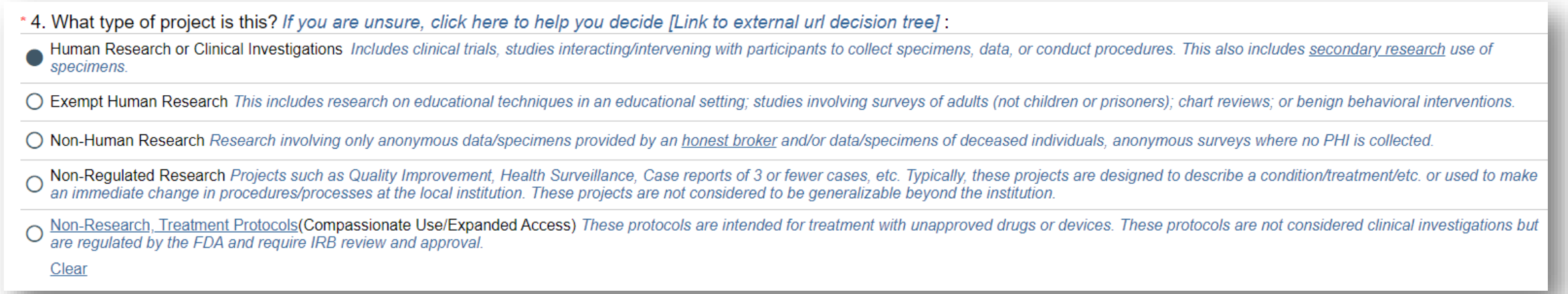
eIRB vs. UTSW ETHOS – Key Features

The following slides outline some differences between eIRB and UTSW ETHOS System:

eIRB	UTSW ETHOS	
Study is initiated in Velos and is then transferred to eIRB.	Study is initiated in the new system is then pushed to Velos.	

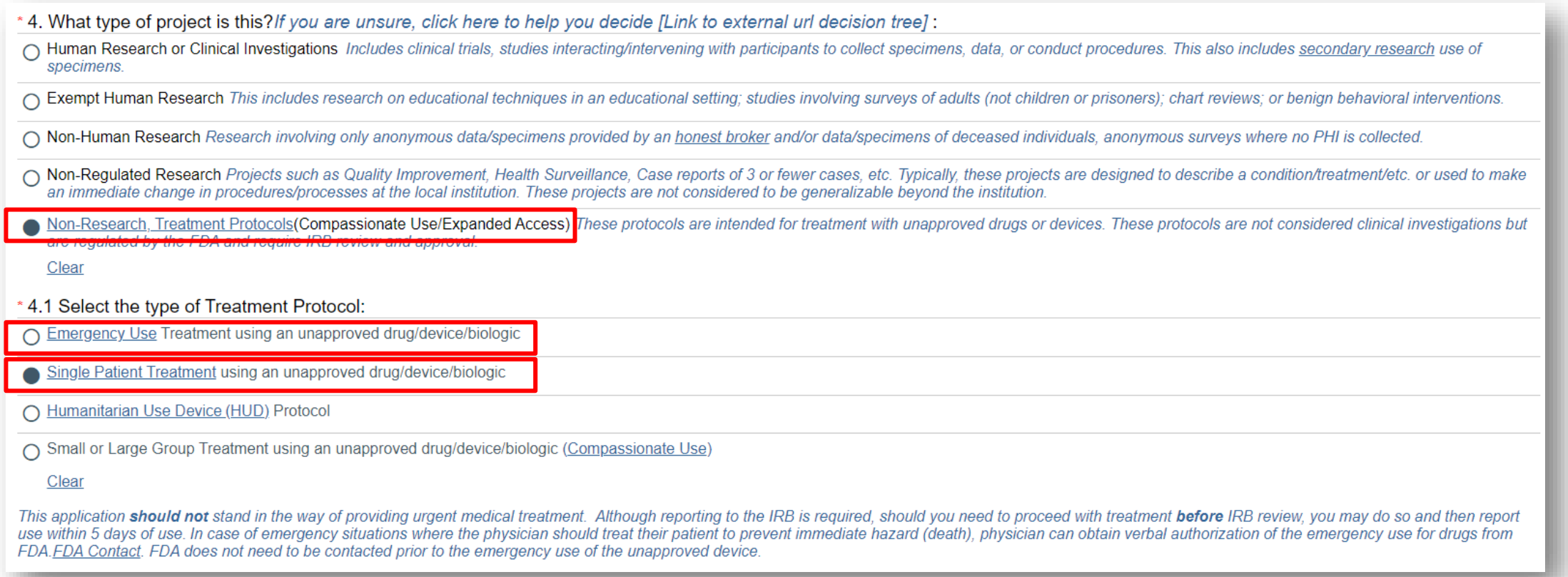
UTSW ETHOS – Key Features

Study type is now part of the intake questions and is expanded to include all potential project types which includes, Human Research or Clinical Investigations, Exempt Research, Non-human Research, Non-regulated Research, and Non-research treatment protocols such as expanded access or compassionate use.



UTSW ETHOS – Key Features

Emergency Use and sIND requests can be submitted in the new ETHOS system (no longer via email).



* 4. What type of project is this? *If you are unsure, click here to help you decide [Link to external url decision tree]* :

- ○ Human Research or Clinical Investigations *Includes clinical trials, studies interacting/intervening with participants to collect specimens, data, or conduct procedures. This also includes secondary research use of specimens.*
- ○ Exempt Human Research *This includes research on educational techniques in an educational setting; studies involving surveys of adults (not children or prisoners); chart reviews; or benign behavioral interventions.*
- ○ Non-Human Research *Research involving only anonymous data/specimens provided by an honest broker and/or data/specimens of deceased individuals, anonymous surveys where no PHI is collected.*
- ○ Non-Regulated Research *Projects such as Quality Improvement, Health Surveillance, Case reports of 3 or fewer cases, etc. Typically, these projects are designed to describe a condition/treatment/etc. or used to make an immediate change in procedures/processes at the local institution. These projects are not considered to be generalizable beyond the institution.*
- ● Non-Research, Treatment Protocols(Compassionate Use/Expanded Access) *These protocols are intended for treatment with unapproved drugs or devices. These protocols are not considered clinical investigations but are regulated by the FDA and require IRB review and approval.*

Clear

* 4.1 Select the type of Treatment Protocol:

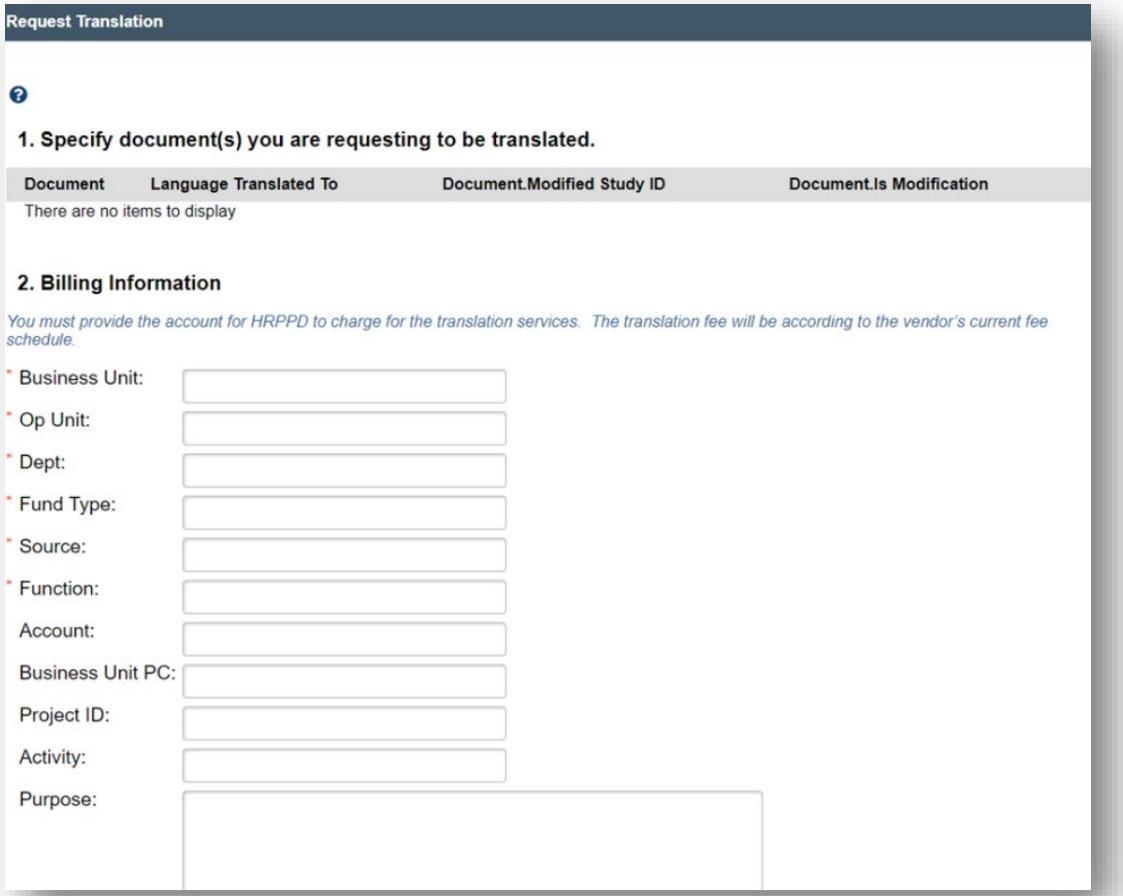
- ○ Emergency Use Treatment using an unapproved drug/device/biologic
- ● Single Patient Treatment using an unapproved drug/device/biologic
- ○ Humanitarian Use Device (HUD) Protocol
- ○ Small or Large Group Treatment using an unapproved drug/device/biologic (Compassionate Use)

Clear

*This application **should not** stand in the way of providing urgent medical treatment. Although reporting to the IRB is required, should you need to proceed with treatment **before** IRB review, you may do so and then report use within 5 days of use. In case of emergency situations where the physician should treat their patient to prevent immediate hazard (death), physician can obtain verbal authorization of the emergency use for drugs from FDA.FDA Contact. FDA does not need to be contacted prior to the emergency use of the unapproved device.*

UTSW ETHOS – Key Features

Translation requests can be done via the UTSW ETHOS system and no longer via email. Click "Request Translation" to initiate the process.



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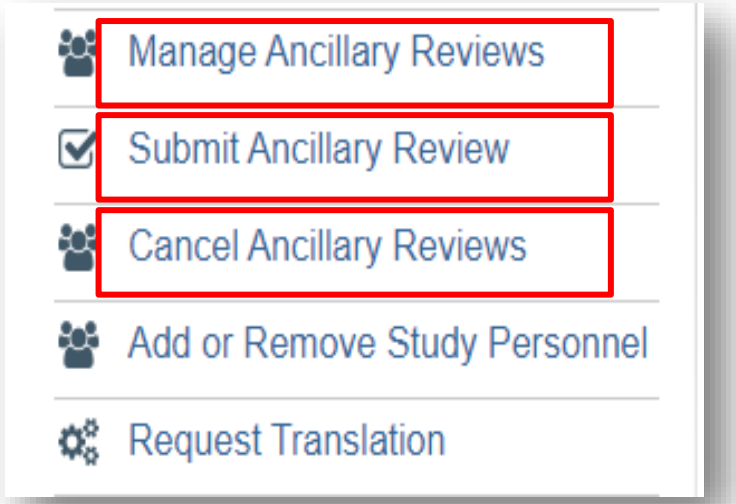
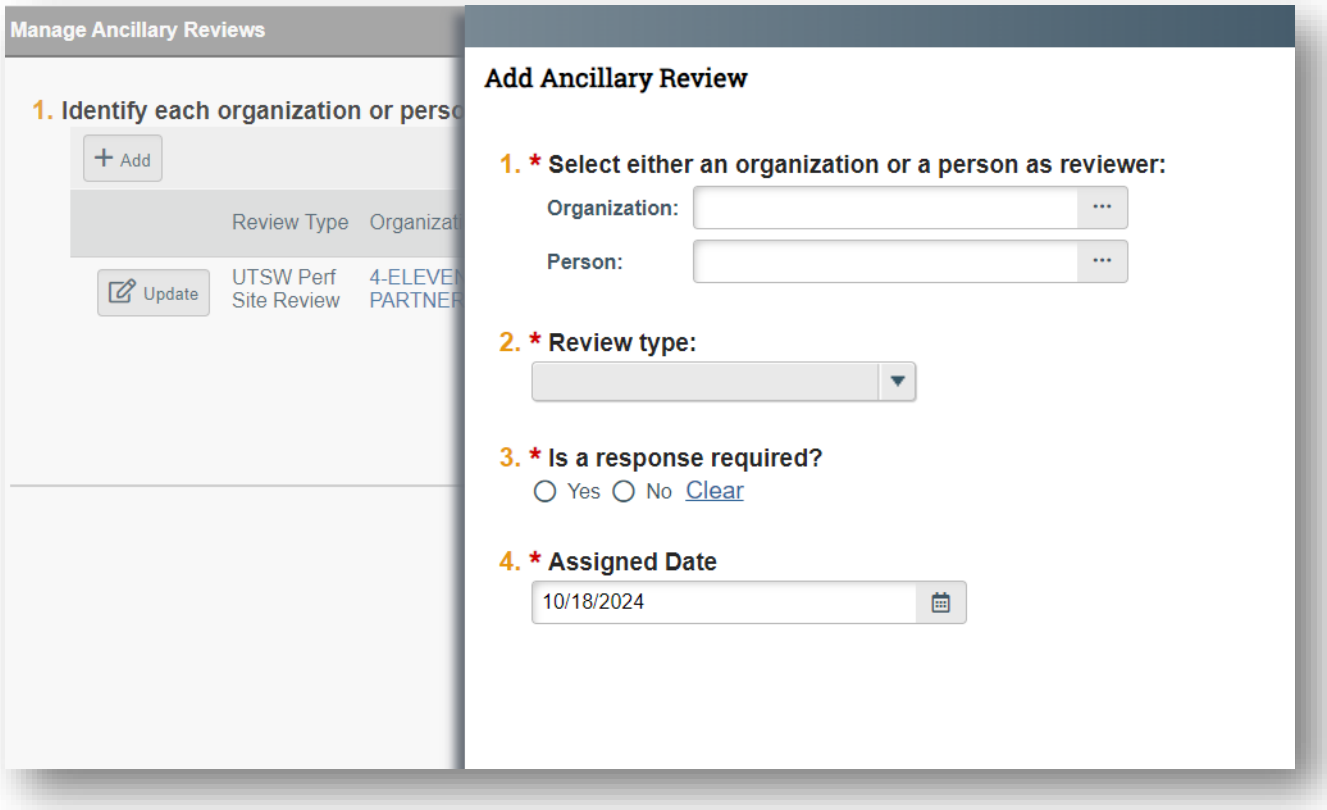
UTSW ETHOS – Key Features

All ancillary reviews (including performance site reviews) may be managed through the UTSW ETHOS system. PRMC and ISAC reviews are the only ones that can be automatically triggered if the smartform questions are answered correctly prior to submission.





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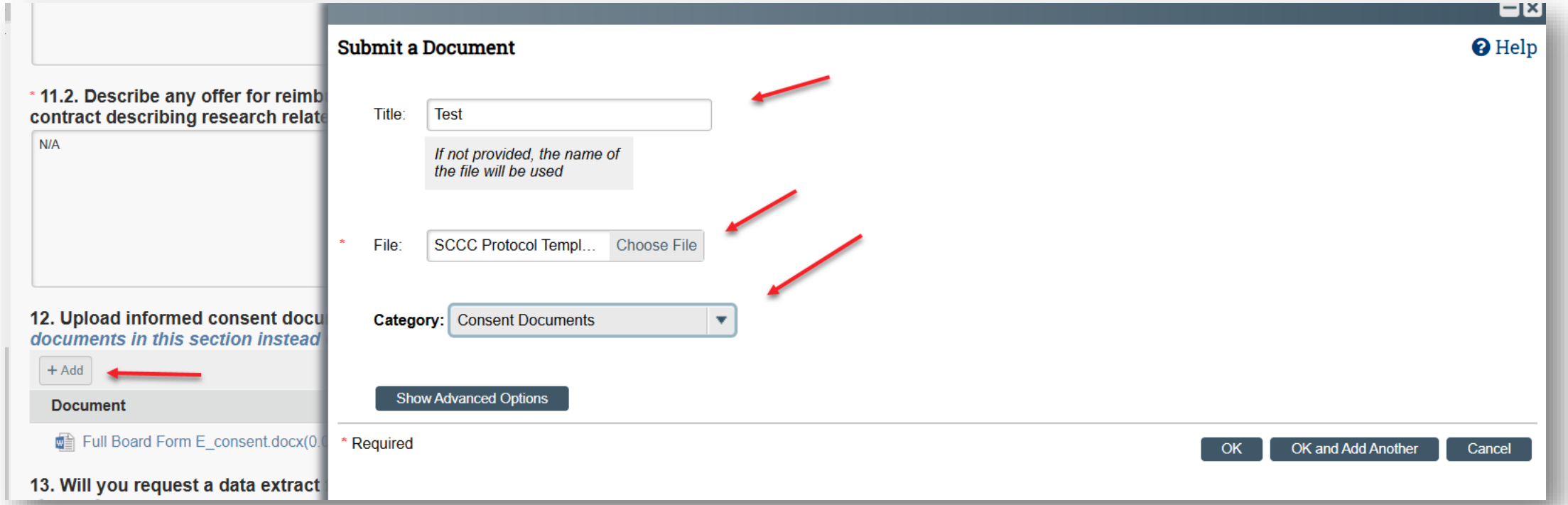
UTSW ETHOS – Key Features

Document uploads can be named whatever you would like to name the document. You will now upload a document and select the appropriate category for the document (e.g., consent form, IB, recruitment material).



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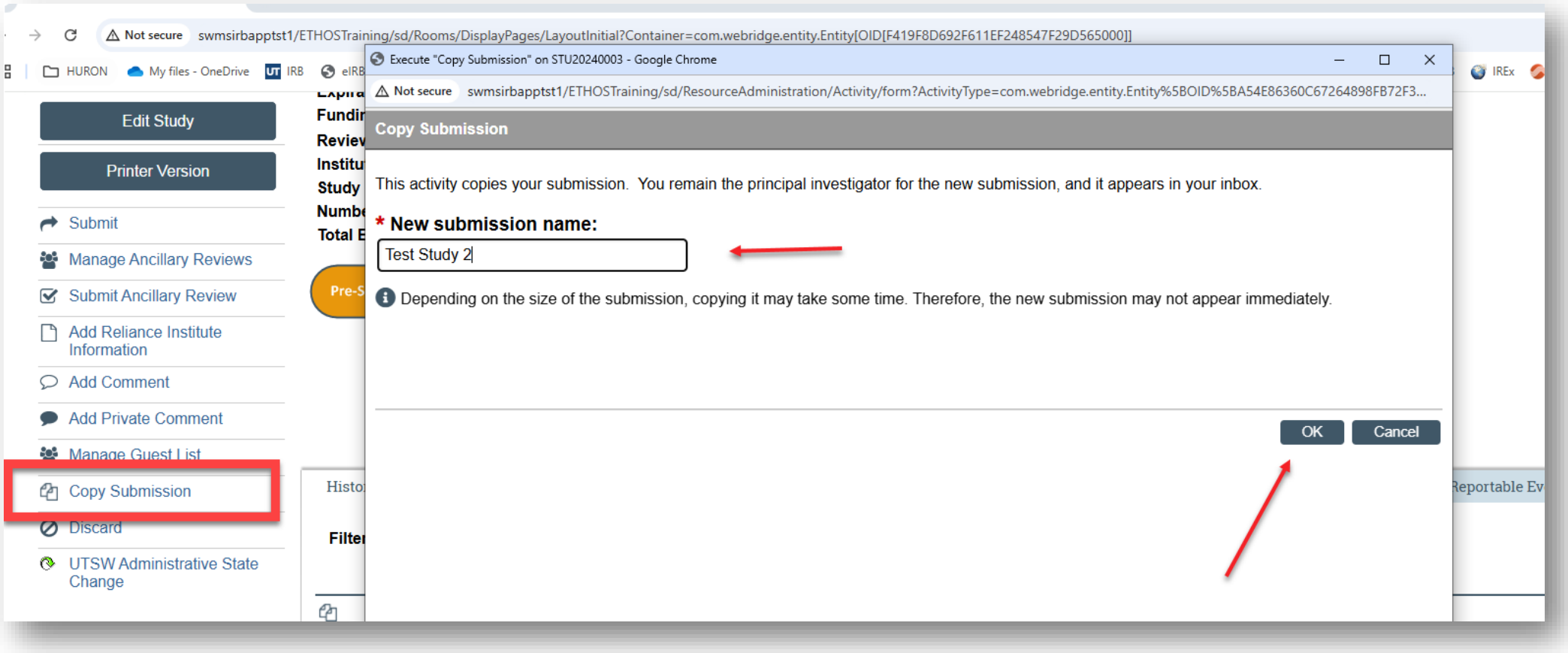
UTSW ETHOS – Key Features

Cloning function



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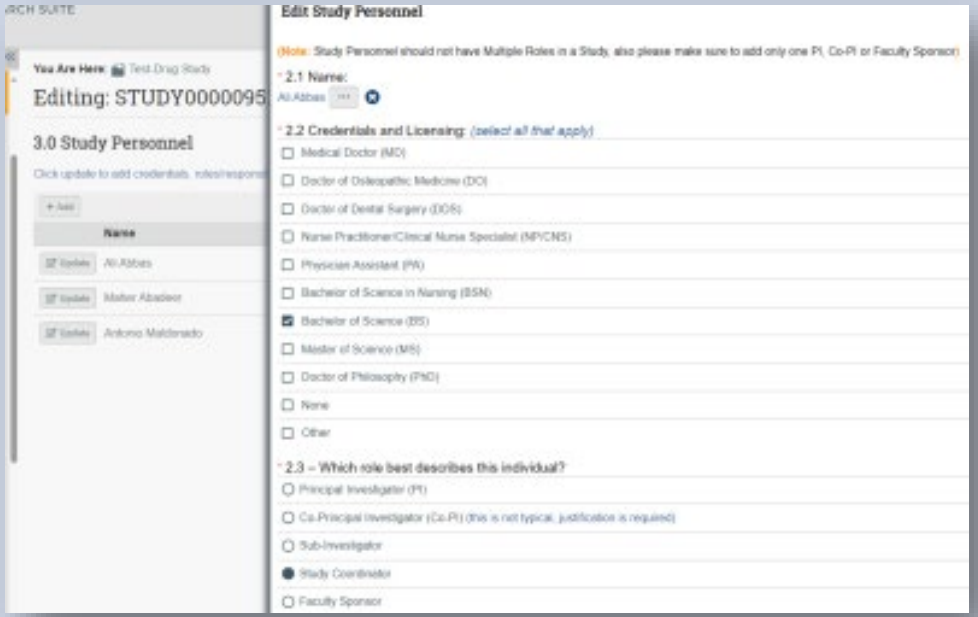
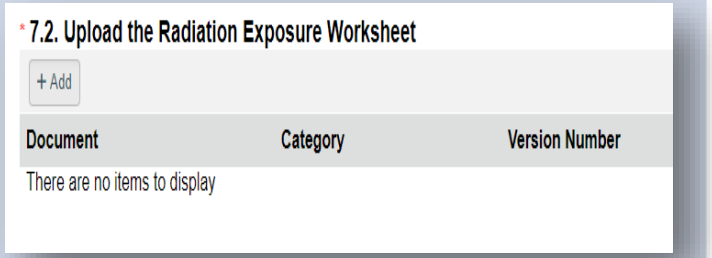
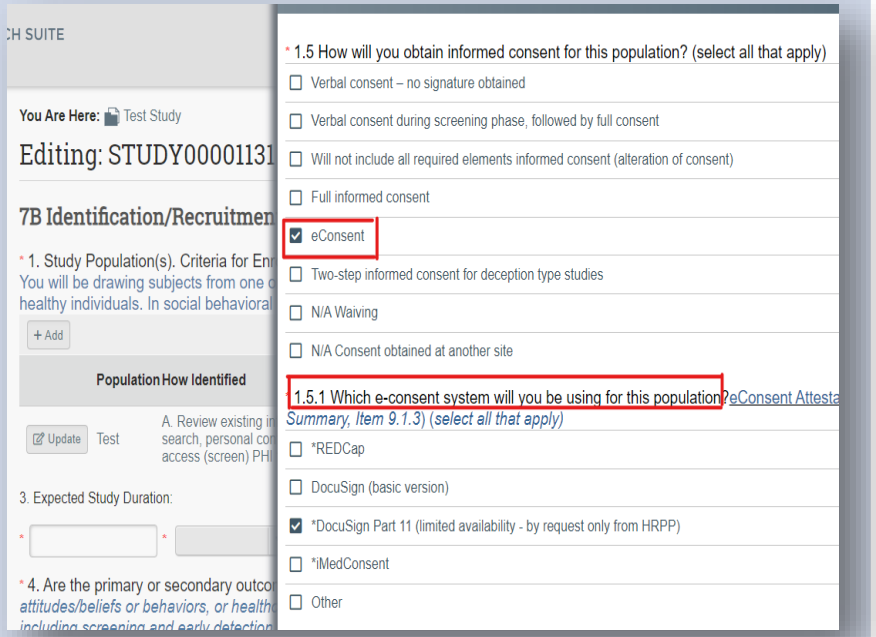
eIRB vs. UTSW ETHOS – Features

eIRB	UTSW ETHOS	
Supplemental forms (Forms B, C, etc.) required to be uploaded throughout the smart form.	Supplemental forms (Forms B, C, etc.) are no longer required. Information from the forms are now embedded throughout the UTSW ETHOS system. *Remaining forms to be attached are consent form templates, information sheets, stand-alone HIPAA Authorization form, protocol forms, Form Z, Form Z1, and the new Radiation Exposure Worksheet for studies that have radiation for research.*	 Example in this slide is personnel information embedded in the smartform instead of Form B

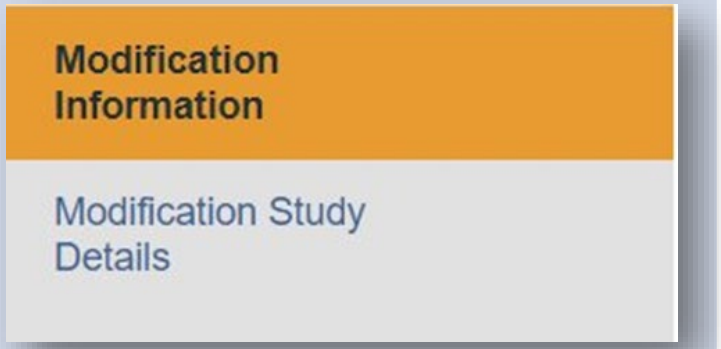
eIRB vs. UTSW ETHOS – Features

eIRB	UTSW ETHOS	
Radiation sections are embedded in eIRB (sections 29-38).	Radiation sections are no longer embedded in UTSW ETHOS system. SHUR will have a template form titled, "**Form RW- Radiation Exposure Worksheet**" for researchers to complete and submit.	

eIRB vs. UTSW ETHOS – Features

eIRB	UTSW ETHOS	
No electronic consent (eConsent) requests in the current system.	eConsent and eConsent systems can be selected in the new UTSW ETHOS system.	

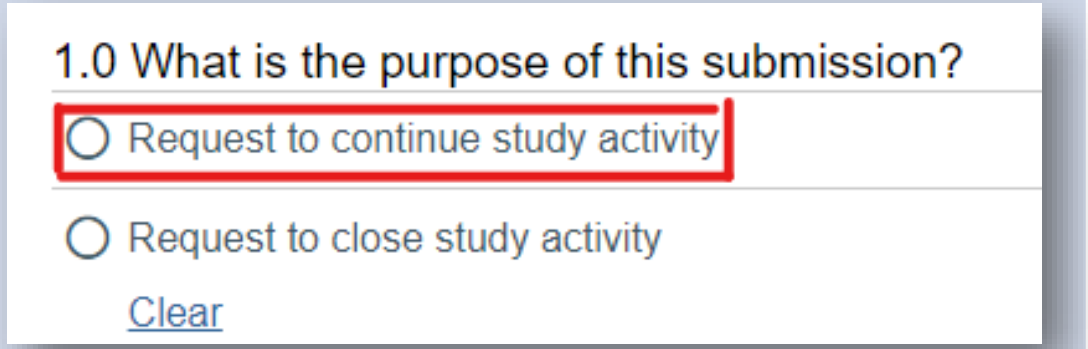
eIRB vs. UTSW ETHOS – Features

eIRB	UTSW ETHOS	
Fourteen (14) modification smartform sections.	The new modification smartform in UTSW ETHOS has only Two (2) Modification smartform Sections: The Modification Information (as above) and the Modification Study Details. Study team summarizes changes in the modification and then make changes in the UTSW ETHOS smartform.	

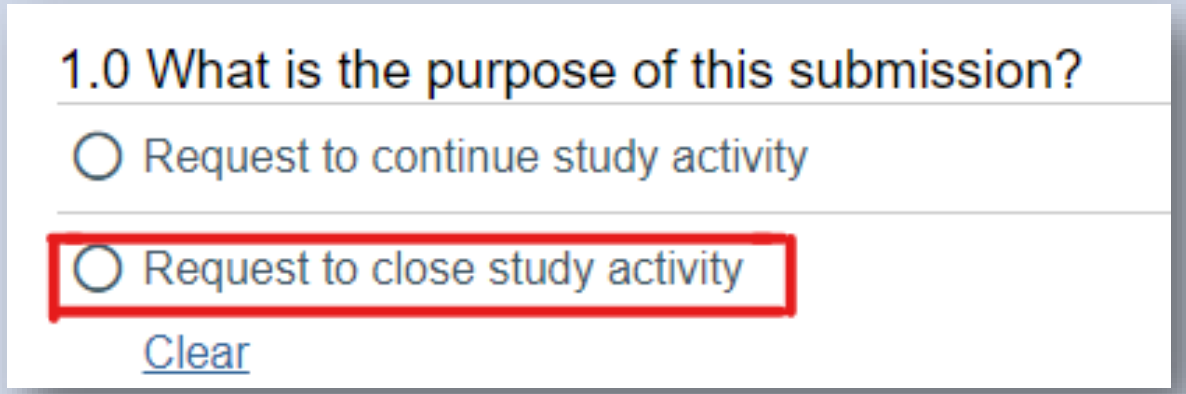
eIRB vs. UTSW ETHOS – Features

eIRB	UTSW ETHOS
CRs could not be submitted at the same time while a Mod was open and vice versa	You may submit both items and the IRB will determine which item needs to be reviewed first.

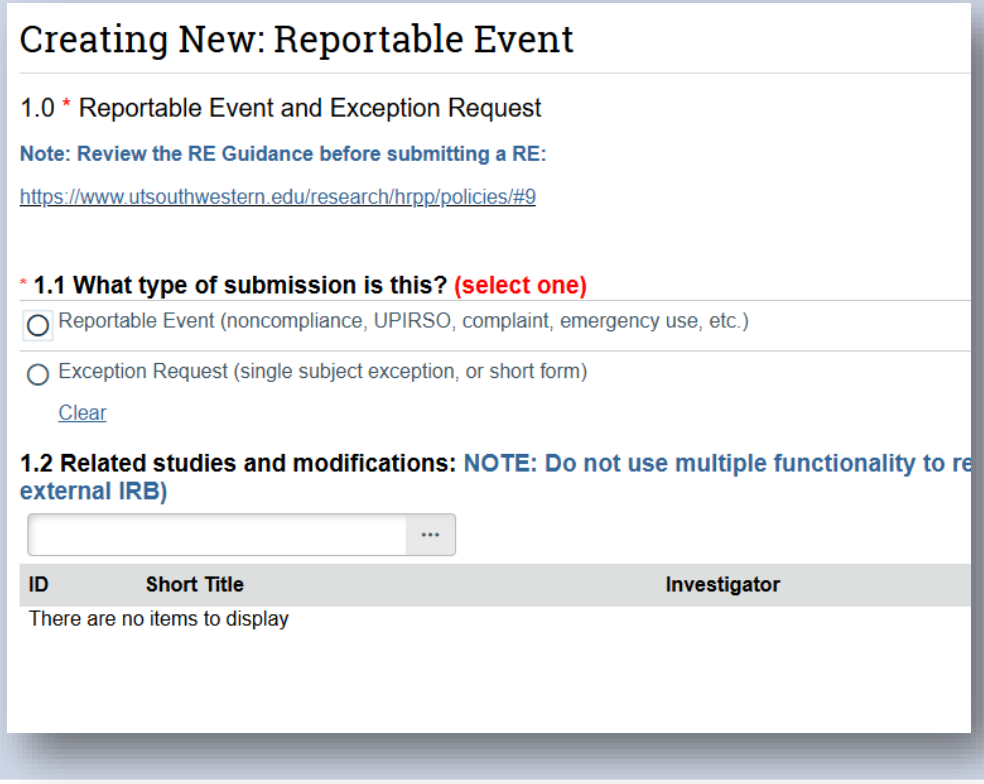
eIRB vs. UTSW ETHOS – Features

eIRB	UTSW ETHOS	
N/A	With this selection, you will either be submitting a CR or an AU.	

eIRB vs. UTSW ETHOS – Features

eIRB	UTSW ETHOS	
N/A	Within the CR / AU smartform you will be able to submit Notice of Study Closures.	

eIRB vs. UTSW ETHOS – Features

eIRB	UTSW ETHOS	
N/A	Reportable Event may be submitted for multiple studies Reporting Emergency Use of an Investigational test article for a single patient	

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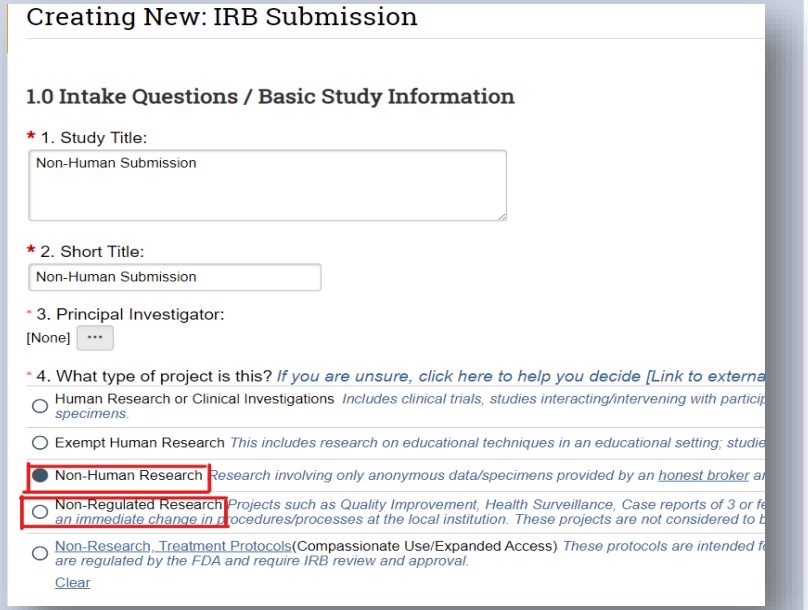
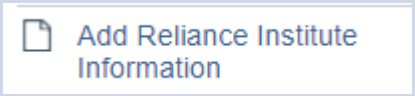
eIRB vs. UTSW ETHOS – Features

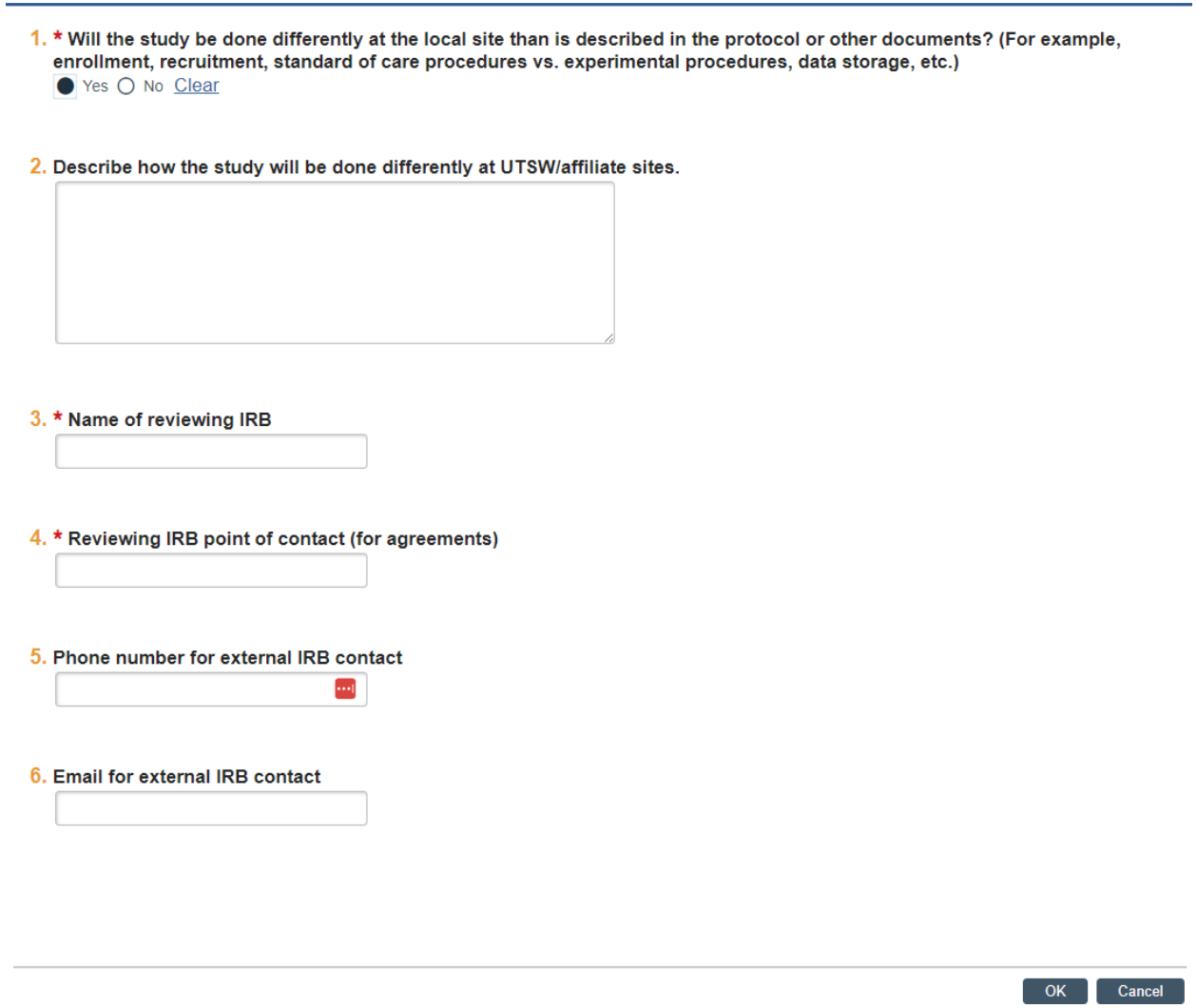
eIRB	UTSW ETHOS	
Non-Human and Non-regulated submissions are submitted by paper and submitted via email.	Non-Human and Non-Regulated Research submission will be submitted in UTSW ETHOS and reviewed like study submissions; the contents of Y1 and Y2 form are in UTSW ETHOS. Determination letters will be generated in UTSW ETHOS.	

eIRB vs. UTSW ETHOS – Features

eIRB	UTSW ETHOS
Determinations for non-Human and Non-Regulated Research submissions are sent via email.	Non-Human Research submissions will receive immediate determinations while Non-Regulated Research submissions will require additional review by the HRPP / IRB Office before the determination letter is sent.

eIRB vs. UTSW ETHOS – Features

eIRB	UTSW ETHOS
Submit a Reliance Request in REDCap	• Submit the Intake page to create the study and push it to Velos. • On the main study workspace, "Add Reliance Institute Information" to send a reliance request to the Reliance Team. 



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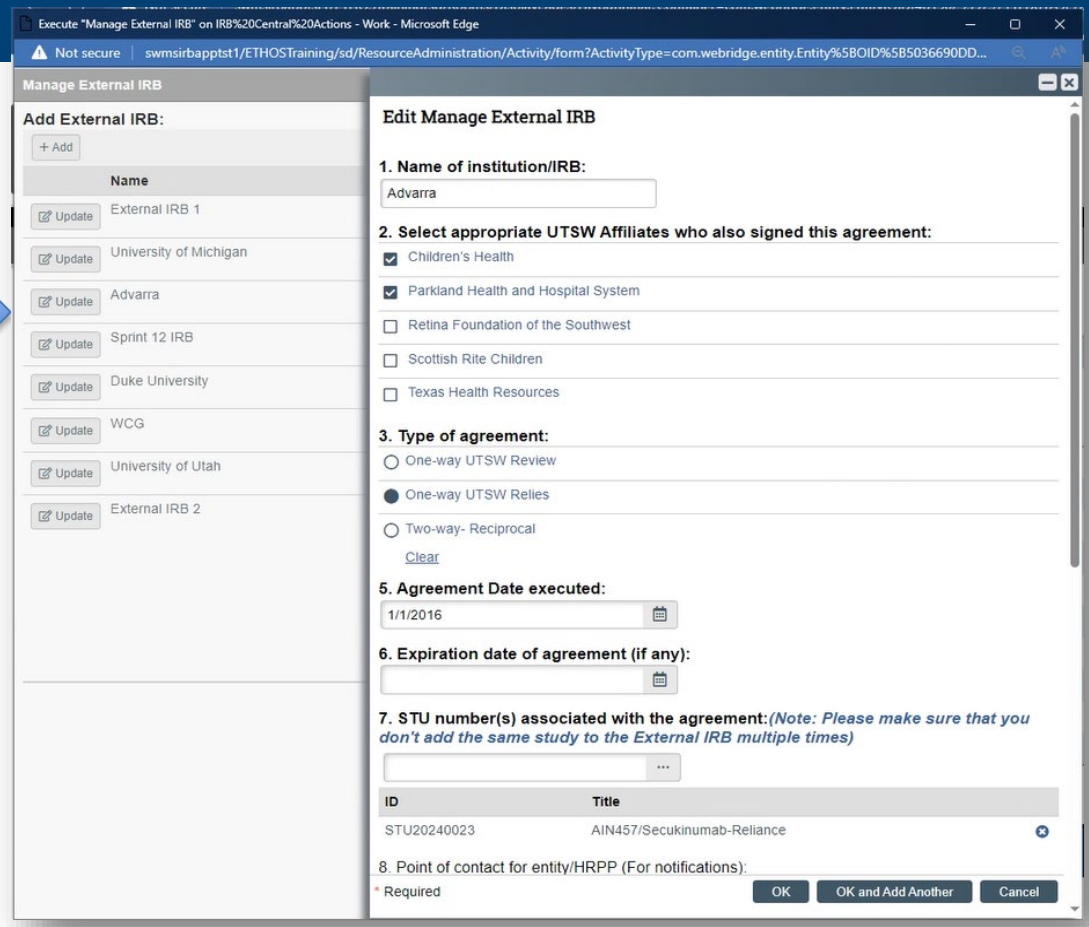
eIRB vs. UTSW ETHOS – Features

UTSW ETHOS – Reliance, Continued

- Once the agreement has been negotiated, the HRPP Reliance Team will add the study to the External IRB in UTSW ETHOS.
- The name of the External IRB will then appear on Page 9.0, Item 1. While you are waiting, you can jump past this point in the submission to complete the rest of the application.



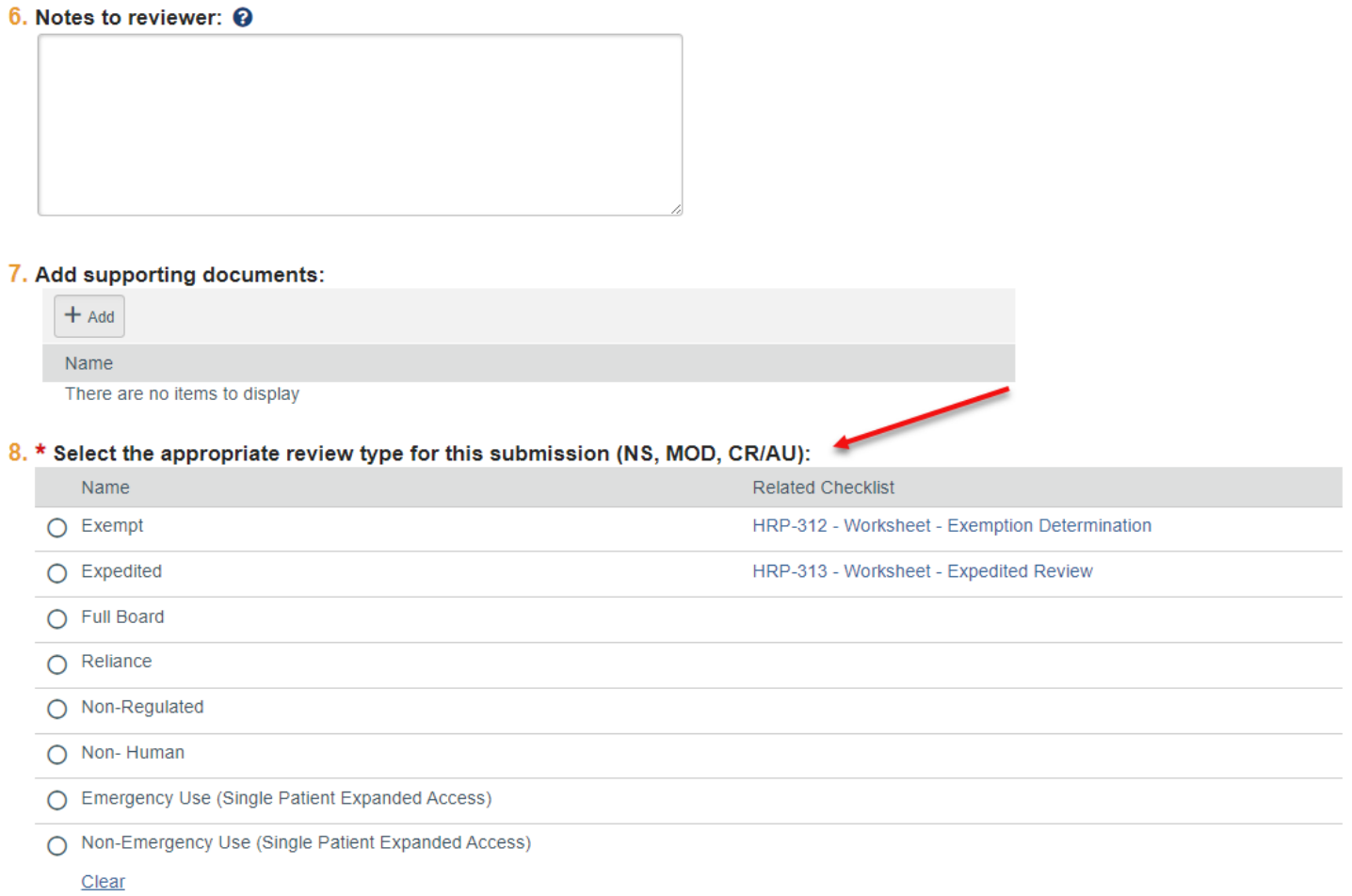
9.0 Relying on a non-UT Southwestern IRB

1. IRB under which this study will be reviewed. *Before moving forward, eIRB Authorization Agreements for all sites selected in question 1 of performance site must be executed with the external IRB . If the IRB name is not listed here, you must save and exit the smartform, and on your main study workspace under "Next Steps," select "Add Reliance Institute Information". Submit the form and once it has been processed, you will be notified.:*

Advarra

eIRB vs. UTSW ETHOS – Features

eIRB	UTSW ETHOS
Selection of the type of study: • Exempt • Expedited • Full Board	• Removed to allow for the research team to focus on completion of the application. • The IRB Analyst will route the study to the appropriate level of review.



Questions?

For Questions, Contact: eIRB@UTSouthwestern.edu

*UTSW ETHOS SharePoint Site:
UTSW ETHOS IRB - Human Research Protection Program - Organization home

*Individuals with UTSW IDs will automatically have access. Individuals at Affiliate Sites may request access by emailing eIRB@UTSouthwestern.edu. The HRPP will send you an invitation.

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