ERMS – IRB Module

Vice President for Research Town Hall

November 15, 2023

Jeannette Watterson, PhD
Director, Institutional Review Board
Office of the Vice President for Research

Brandie Otten
Associate Director, Institutional Review Board
Office of the Vice President for Research

UT Health San Antonio | Enterprise Research Management System (ERMS)

Agenda

- ERMS and Implementation Update
- Overview of ERMS-IRB Module
- How to access additional information
- ERMS-IRB Demonstration
- Important Deadlines
- Questions

Note: Slides will be made available on the VPR ERMS website and the ERMS SharePoint site.

UT Health San Antonio | Enterprise Research Management System (ERMS)

ERMS Overview

The Enterprise Research Management System (ERMS) is a comprehensive and integrated software solution to create an information portal for research administrative support, relieve administrative burden and free up time for mission-focused activities.

ERMS is part of our commitment to provide:

- Exceptional research administration service delivery
- Increased transparency and improved user experience
- Automated workflows

UT Health San Antonio | Enterprise Research Management System (ERMS)

ERMS – IRB Module

- Will replace current email submissions and access to approved documents through ORCA – December 2023
- Purpose:
  - Manage human subjects research protocols within the IRB Office
  - Single electronic regulatory system for internal and external IRB studies
- Comply with federal, state, and institutional requirements
- *Change Impact*: Single point of entry system, integrated management of regulatory accountability processes, data reporting and extraction.

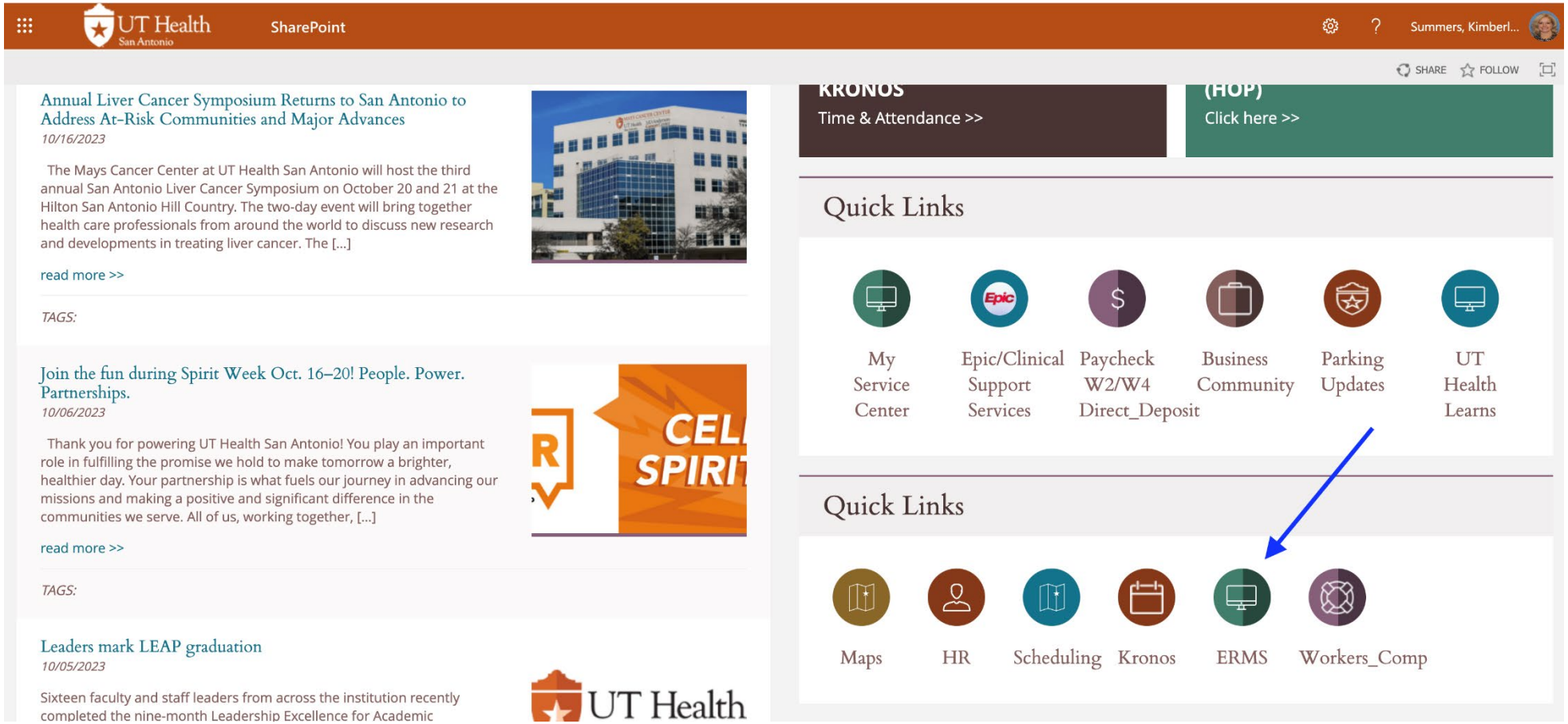
UT Health San Antonio | Enterprise Research Management System (ERMS)

ERMS – IRB Module: Terminology

- **IRB Reliance Coordinator –** formerly OCR analyst; administrative team dedicated to coordination of protocols reviewed by an external IRB.
- **IRB Coordinator**– formerly IRB analyst; administrative team dedicated to coordination of protocols reviewed by UT Health SA IRB.
- **Modification –** Amendment; any change in study involving protocol, procedures, personnel, or other item requiring IRB/IRB office review.
- **Reportable New Information (RNI) –** Prompt Report; report by PI or study team notifying the institution and the designated IRB when specific issues are identified, e.g., noncompliance, unanticipated problem, etc.
- **Clarification Requests –** when an IRB coordinator requests additional information from the study team.
- **Ancillary Review –** study review conducted in parallel by an ancillary office, e.g., Radiation Safety, University Health
- **pSite** – participating site; external study location engaged in study under UT Health SA IRB oversight

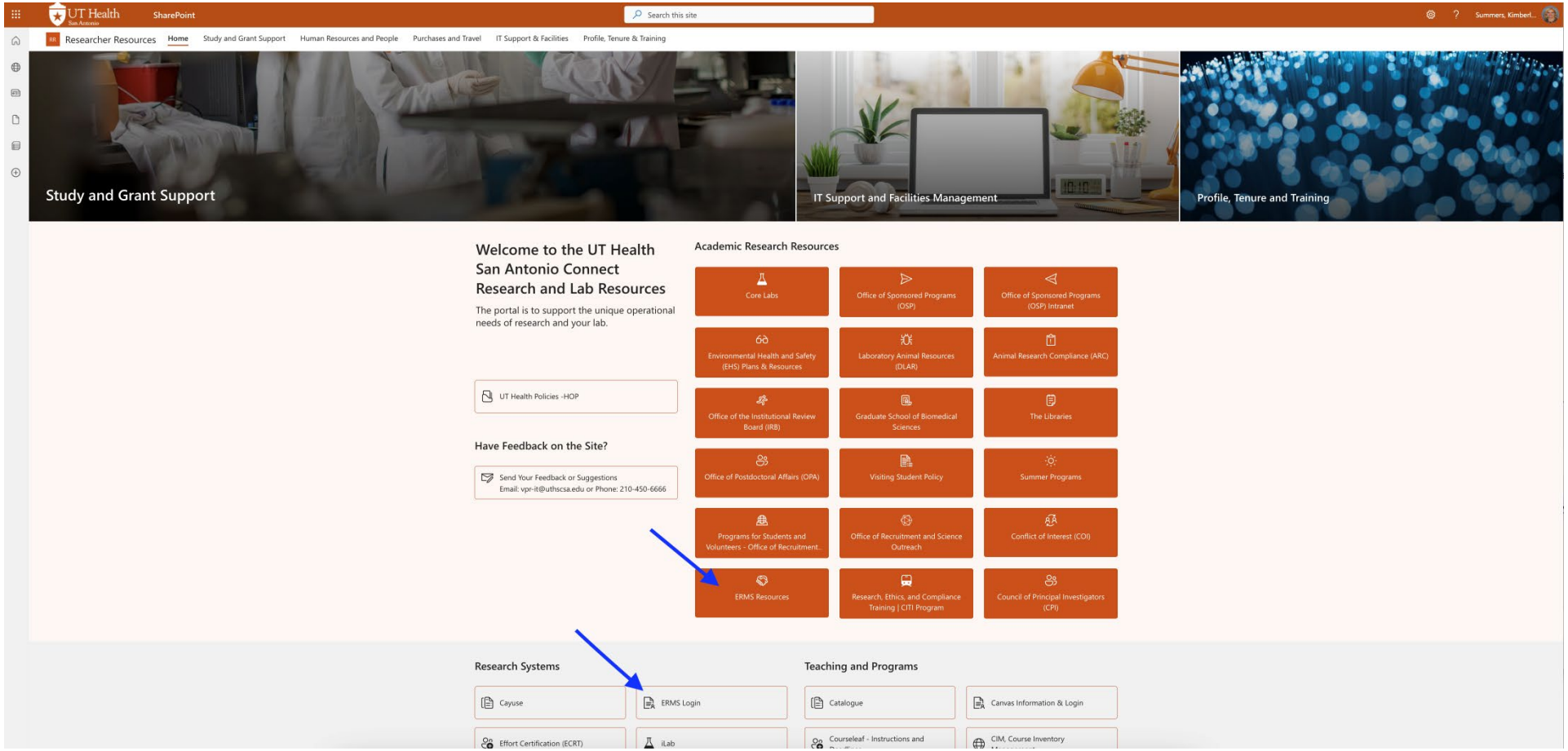
UT Health San Antonio | Enterprise Research Management System (ERMS)

ERMS Log-In From My UT Health



UT Health San Antonio | Enterprise Research Management System (ERMS)

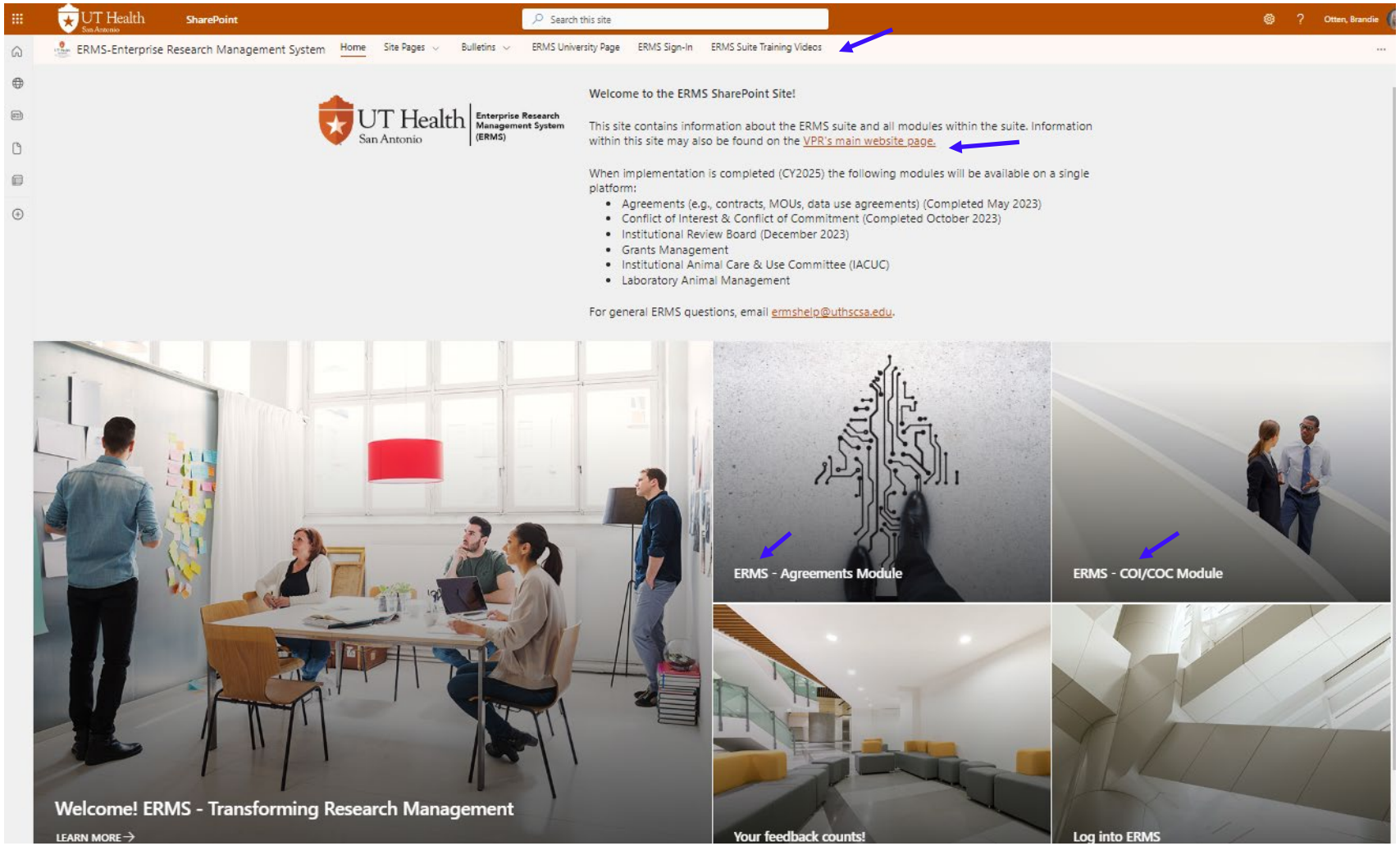
ERMS Log-In From UT Health Connect Research



[My UT Health]

UT Health San Antonio | Enterprise Research Management System (ERMS)

ERMS SharePoint Site



UT Health San Antonio | Enterprise Research Management System (ERMS)

ERMS – IRB Module: Information

https://www.uthscsa.edu/vpr/services/erms

Find additional information and updates:

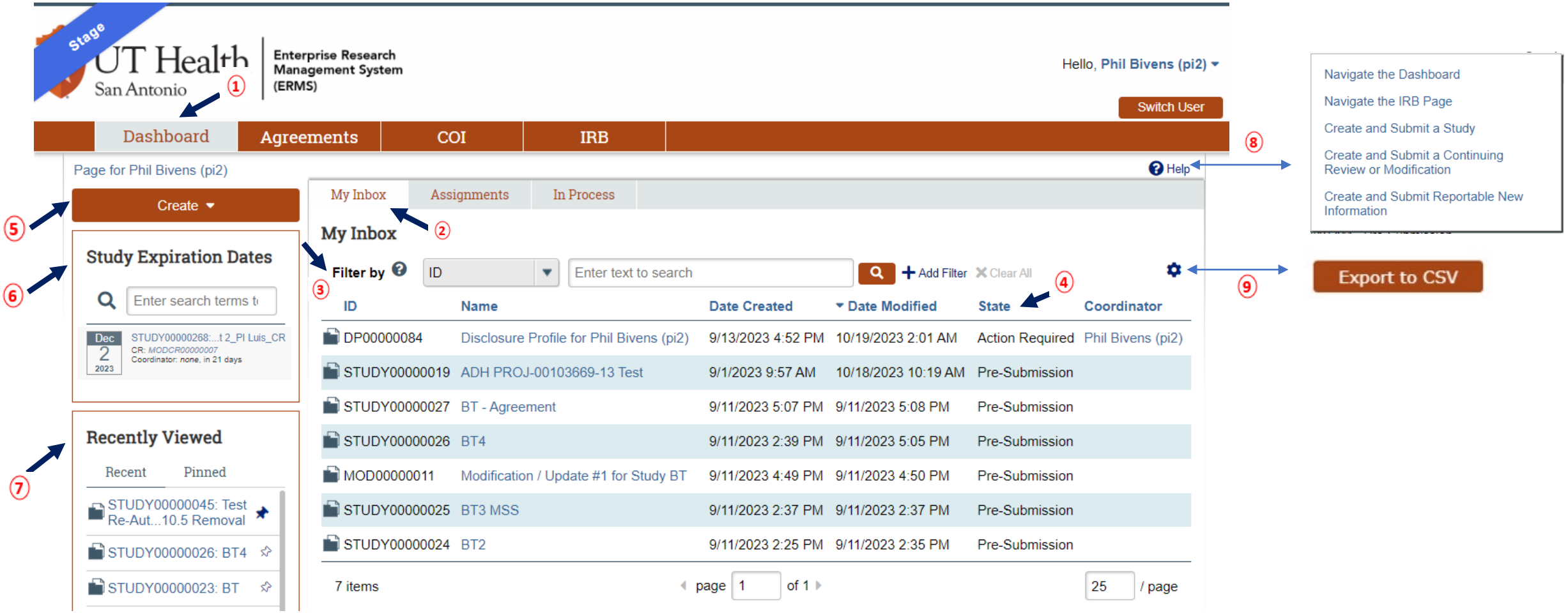
- Online
- Email bulletins
- Contact us via phone or email

Email: IRB@uthscsa.edu or IRBReliance@uthscsa.edu

UT Health San Antonio | Enterprise Research Management System (ERMS)

ERMS Dashboard

UT Single Sign On (SSO)

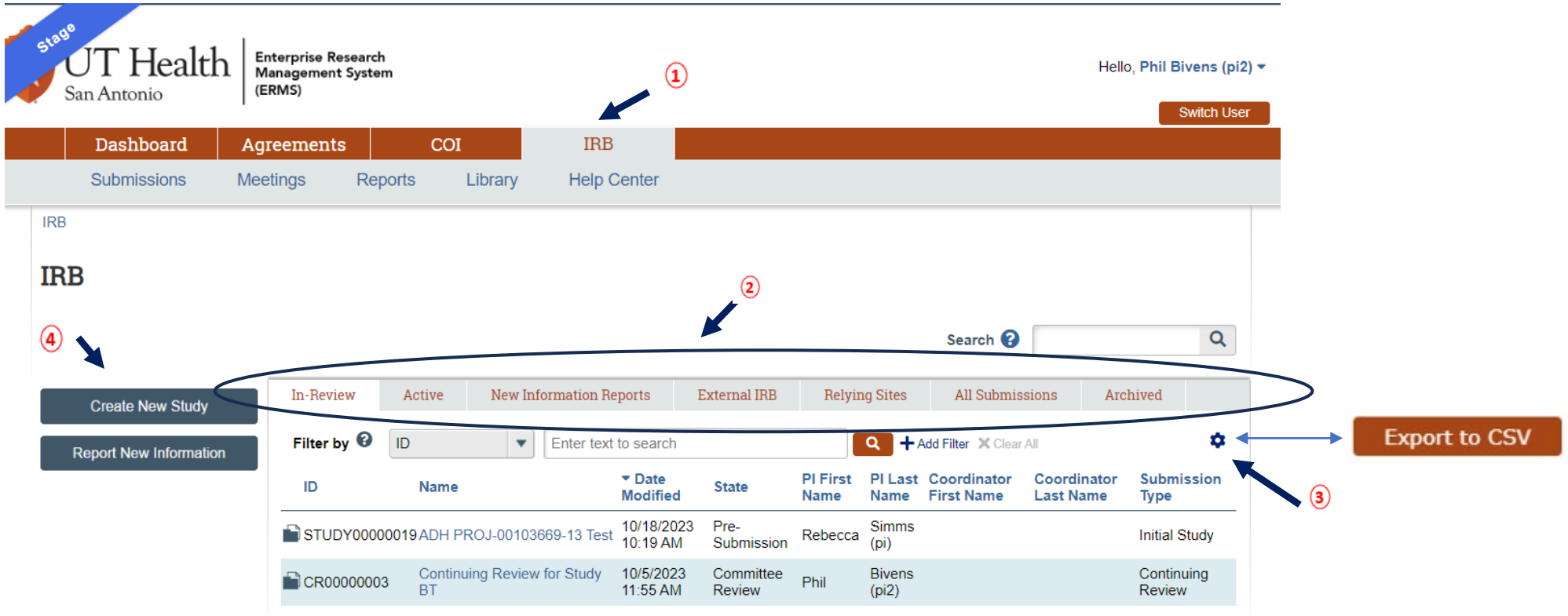


ID	Name	Date Created	Date Modified	State	Coordinator
DP00000084	Disclosure Profile for Phil Bivens (pi2)	9/13/2023 4:52 PM	10/19/2023 2:01 AM	Action Required	Phil Bivens (pi2)
STUDY00000019	ADH PROJ-00103669-13 Test	9/1/2023 9:57 AM	10/18/2023 10:19 AM	Pre-Submission	
STUDY00000027	BT - Agreement	9/11/2023 5:07 PM	9/11/2023 5:08 PM	Pre-Submission	
STUDY00000026	BT4	9/11/2023 2:39 PM	9/11/2023 5:05 PM	Pre-Submission	
MOD00000011	Modification / Update #1 for Study BT	9/11/2023 4:49 PM	9/11/2023 4:50 PM	Pre-Submission	
STUDY00000025	BT3 MSS	9/11/2023 2:37 PM	9/11/2023 2:37 PM	Pre-Submission	
STUDY00000024	BT2	9/11/2023 2:25 PM	9/11/2023 2:35 PM	Pre-Submission	

7 items page 1 of 1 25 / page

UT Health San Antonio | Enterprise Research Management System (ERMS)

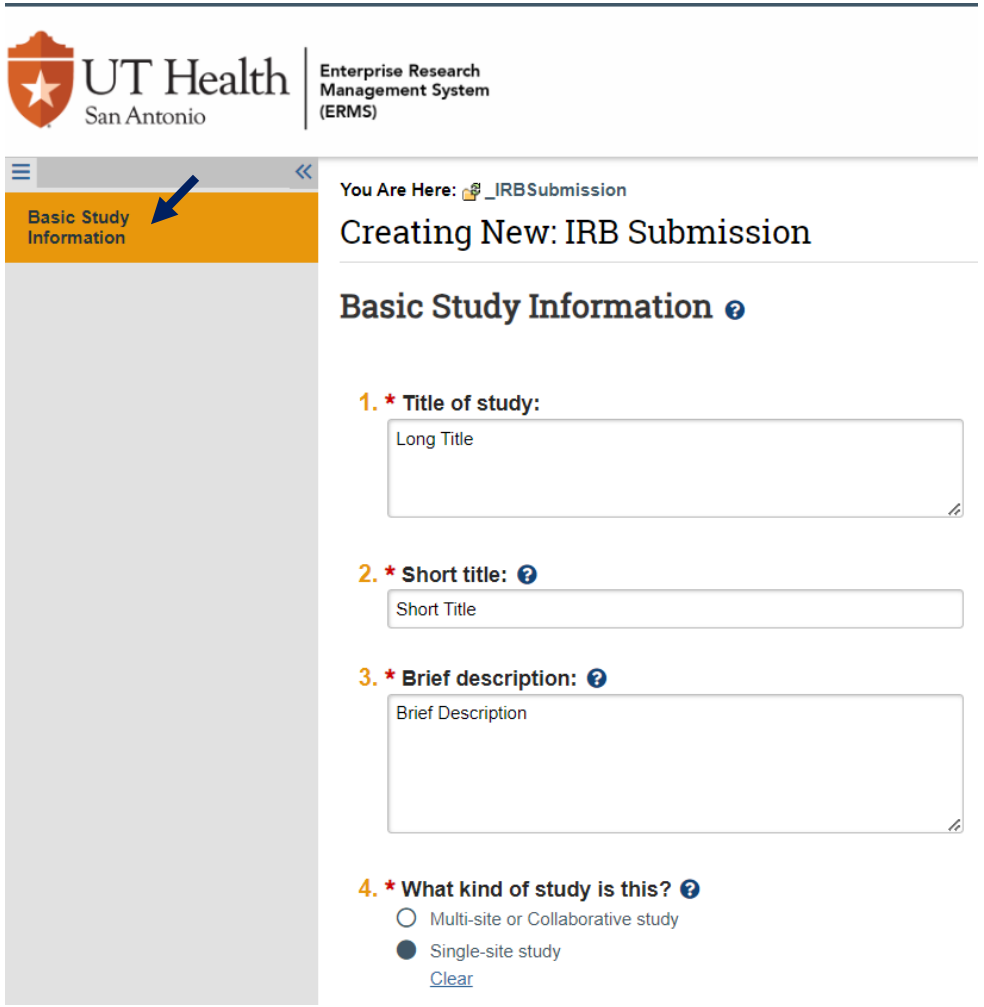
ERMS IRB Module



- **In-Review:** Submissions undergoing UT Health SA IRB review.
- **Active:** All approved UT Health SA IRB studies.
- **New Information Reports**: All Reportable New Information (RNI) submissions, in any state.
- **External IRB:** All submissions undergoing External IRB Reliance review, in any state.
- **Relying Sites:** All participating sites relying on UT Health SA IRB as the single IRB of record.
- **All Submissions:** All submissions, in any state.
- **Archived:** All closed, disapproved, discarded, and terminated submissions.

UT Health San Antonio | Enterprise Research Management System (ERMS)

Create New Study – UT Health SA IRB



Short Title

- Select a short title for your study. You can use the sponsor's short title or any other unique name. As a guideline, keep it shorter than 50 characters.
- The short title identifies the study throughout the IRB system, such as in your inbox and in the IRB's list of submissions to review.

Brief Description

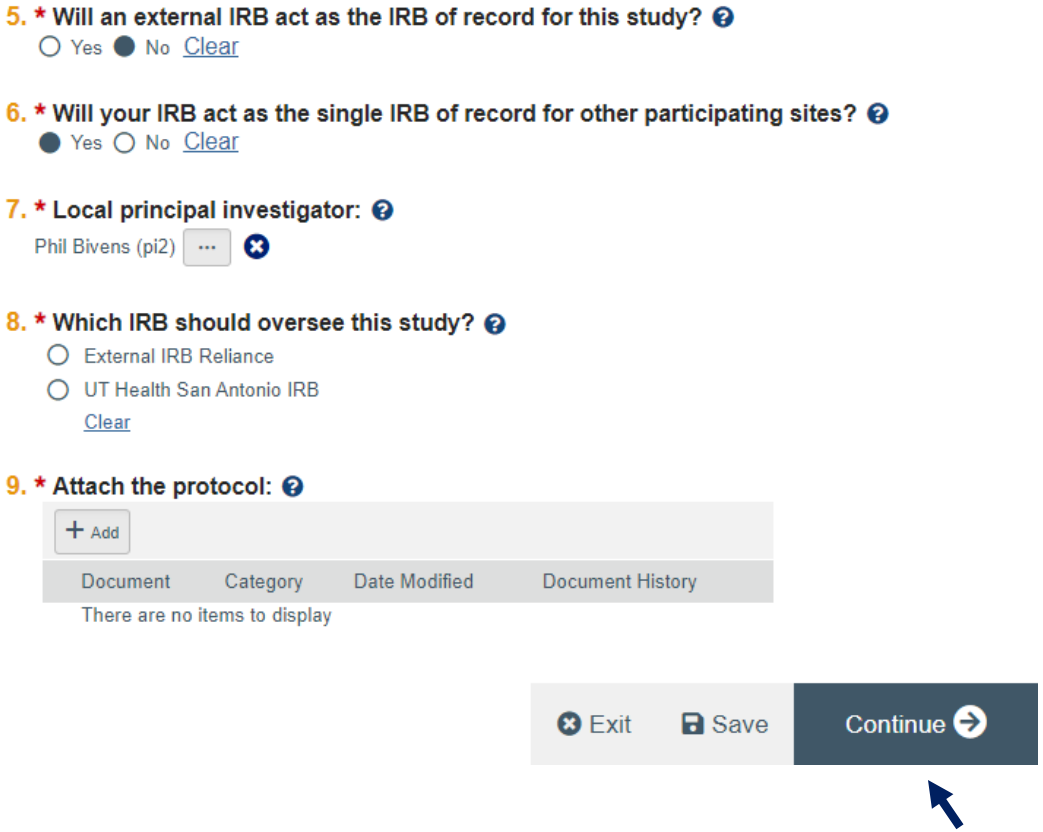
- In a few words, summarize the central question the research is intended to answer (e.g. primary objects / methods used.
- For example: This is a <drug study, vaccine study, chart review, bio-specimen analysis, survey, or questionnaire study> that will examine...

Kind of Study

- A multi-site or collaborative research study is one where two or more institutions collaborate to complete the research outlined in a specific protocol. Must select when participating sites are relying on UT Health SA IRB as the sIRB of record.
- A single-site study is one where all research activities occur at one institution. List studies involving affiliate sites (VA, UH) as a single-site study.

UT Health San Antonio | Enterprise Research Management System (ERMS)

Basic Study Information



External IRB of Record

Select 'Yes' if using an external IRB of record (e.g. Advarra, WCG IRB, UTSW) .

Is Your IRB the IRB of Record?

Select 'Yes' if the IRB at your institution will be responsible for reviewing this submission on behalf of all sites participating in this study.

Local Principal Investigator

Select the local principal investigator for this study or participating site. If this is a multi-site or collaborative research study for which your IRB will be serving as the IRB of record, then select the name of the principal investigator responsible for the entire conduct of the study. You will enter individual site principal investigators on the site records.

IRB to Oversee Study

- Select External IRB Reliance if using an external IRB of record (e.g. Advarra, WCG IRB, UTSW).
- Select UT Health San Antonio IRB if using the local UT Health SA IRB as the IRB of record.

Attach the Protocol

Attach protocol using the template from the following diagram:

UT Health San Antonio | Enterprise Research Management System (ERMS)

Protocol Template Diagram

Attach the Protocol - Attach protocol using the template from the following diagram:

Non-human subjects or non-regulated research	Exempt Determination	Expedited Review non-experimental	Expedited Review experimental	Full Board Review	Investigator-Sponsor	Emergency Use of Investigational Agent
IRB Office Review		IRB Approval				IRB Notification
Examples: -Quality Improvement -Health surveillance -Program evaluation -Use of deidentified data or specimens -Use of commercially available samples or publicly available data	Examples: -Chart reviews -Surveys -Comparing educational methods -Benign behavioral interventions -Research on specimens collected for other purposes	Examples: -Collection of blood by venipuncture -Collection of non-invasive biological specimens -Collection of non-invasive measurements -In-vitro diagnostic testing	Examples: -Use of minimal risk experimental procedures including approved drugs or devices which do not require IND or IDE	Examples: -All greater than minimal risk research -Clinical trials -Any research use involving radiation -Any research use of invasive procedures	Examples: -FDA IND or IDE held by local investigator	Use the below checklists to determine whether the use of the drug or device qualifies as Emergency Use
HRP-503a – Template – Protocol – Nonhuman determination	**HRP-503b – Template – Protocol – Exempt Research**	**HRP-503c – Template – Protocol – Expedited Study non-experimental**	**HRP-503d – Template – Protocol – Expedited Study experimental**	**HRP-503 – Template – Protocol – Full Board Study**	**HRP-503e – Template – Protocol – Investigator IND/IDE**	**HRP-503f – Template – Drug Emergency Use** **HRP-503g – Template – Device Emergency Use**

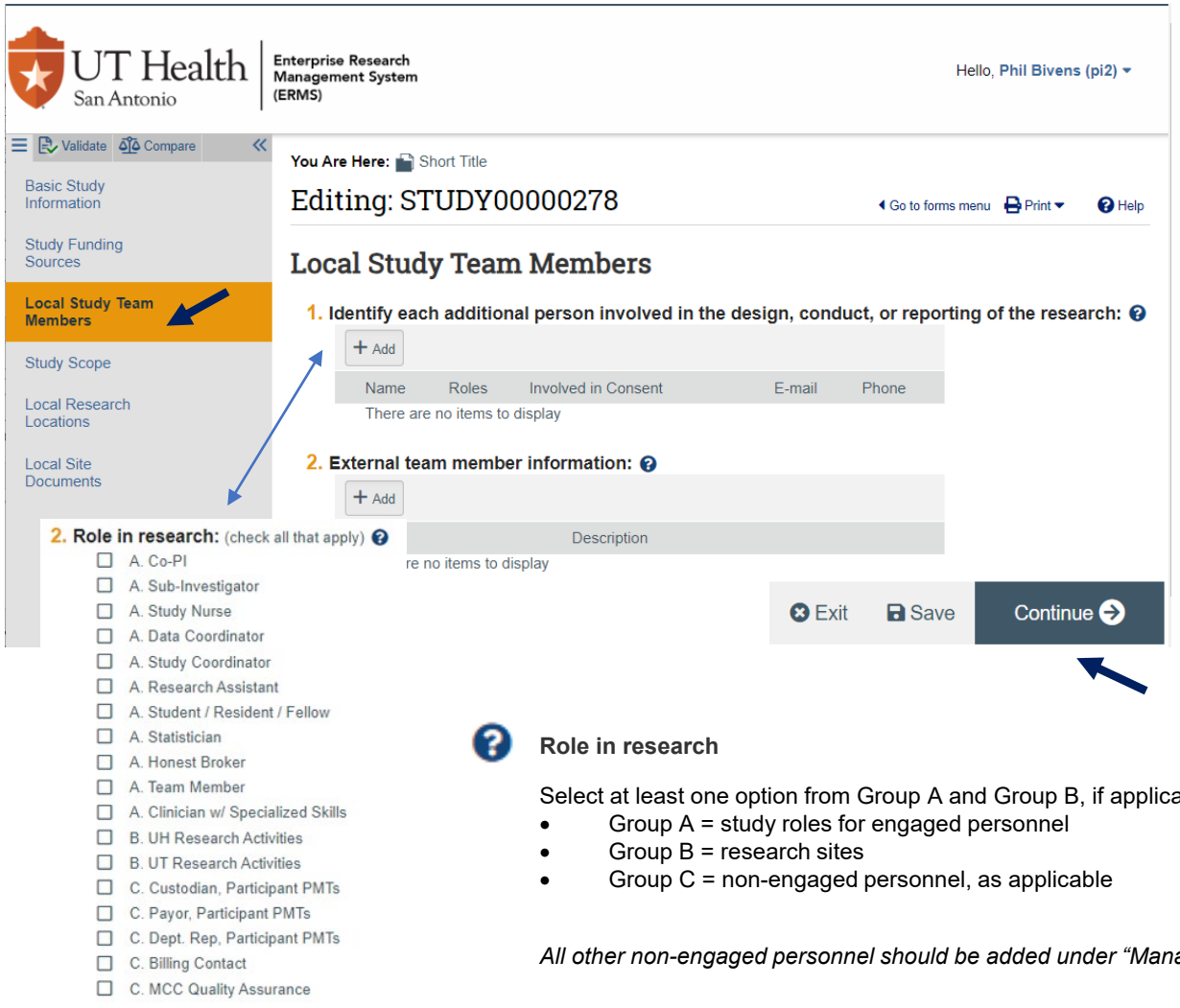
UT Health San Antonio | Enterprise Research Management System (ERMS)

Study Funding Sources

Funding Sources Page

Identify all external funding sources, such as industry sponsors and government agencies. If funding comes from a specific internal funding program, also identify that funding source.

Local Study Team Members - Internal



Study Team Members

UT Health SA employees	Add UT Health SA employees who will be interacting with human subjects or accessing identifiable private information (engaged in research) Add UT Health SA employees who will be the custodian, payor, and department representative for participant payments (if applicable). Add UT Health SA employee who will be the billing contact for the study (if applicable).
UH employees	Do not add UH employees. They will be listed on a separate UH specific personnel form.
VA/WOC employees	Do not add VA/WOC employees. They will be listed within the VA IRBNet application.
IMPORTANT: Do not list study team members from other sites for a multi-site study. Other sites involved in multi-site studies will add their own information about local study team members.	

Tips: If you have difficulty finding the person in the list, try typing the beginning of the first or last name. Contact the IRB staff for assistance if a person is not listed in the system.

Role in research

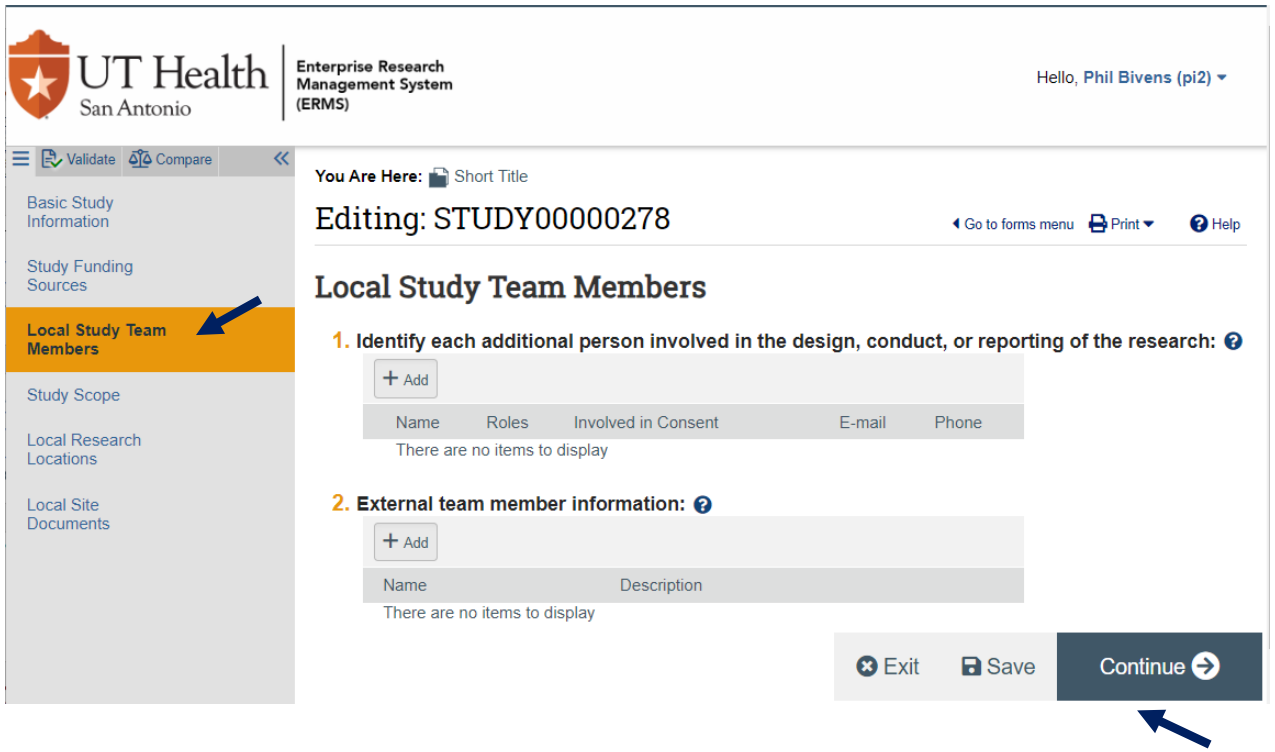
Select at least one option from Group A and Group B, if applicable.

- Group A = study roles for engaged personnel
- Group B = research sites
- Group C = non-engaged personnel, as applicable

All other non-engaged personnel should be added under "Manage Guest List".

UT Health San Antonio | Enterprise Research Management System (ERMS)

Local Study Team Members - External

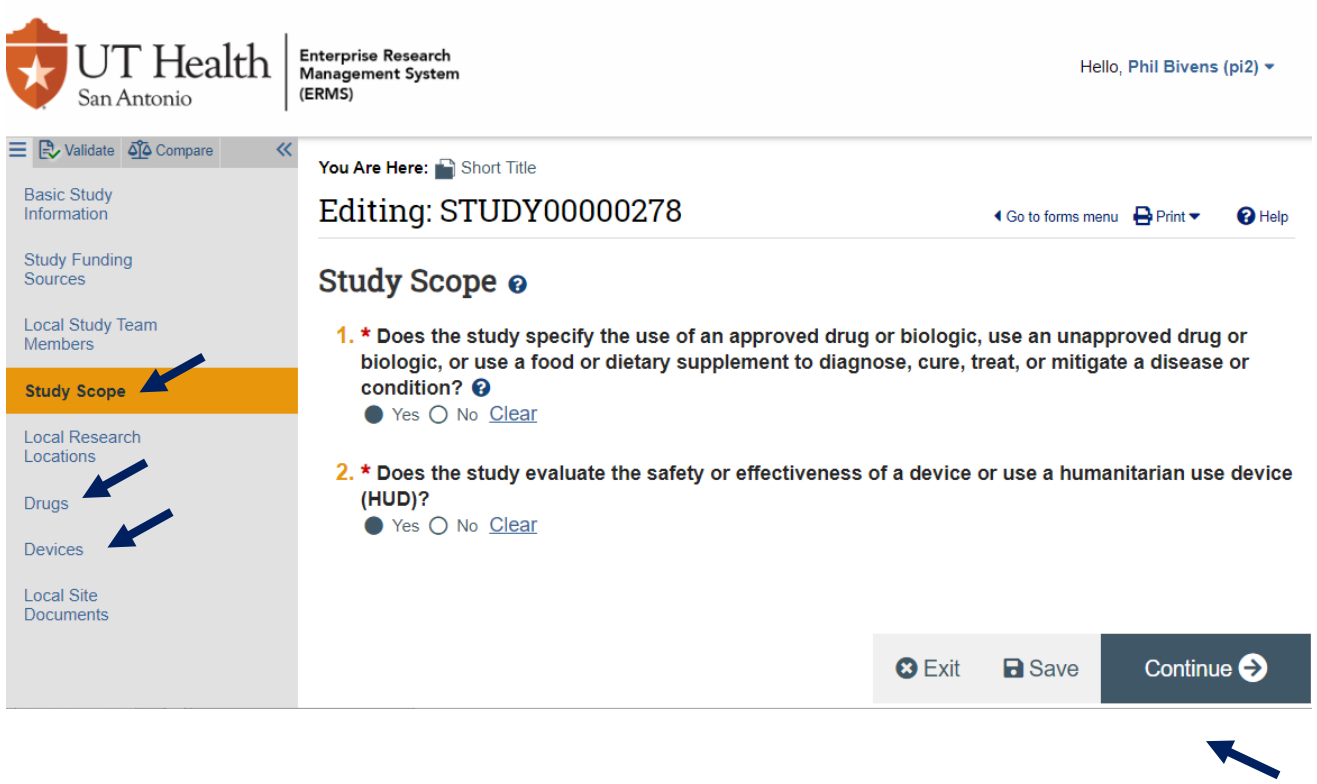


External Team Member Information

DO	DON'T
• List University Health employees (e.g. @uhtx.com email) on the **University Health Personnel Form**.	• Do not add UT Health San Antonio employees. "UH Research Activities" should be selected in the study team member roles if applicable. • Do not add VA employees/WOCs. They will be listed within the VA IRBNet application and should not be included here. Add study team members from other sites for a multi-site study. Other sites involved in multi-site studies will add their own information about local study team members.
IMPORTANT: Do not add information about team members you were able to select in the previous question. For people listed in the system, the information should be added to their profiles in the system instead.	

UT Health San Antonio | Enterprise Research Management System (ERMS)

Study Scope



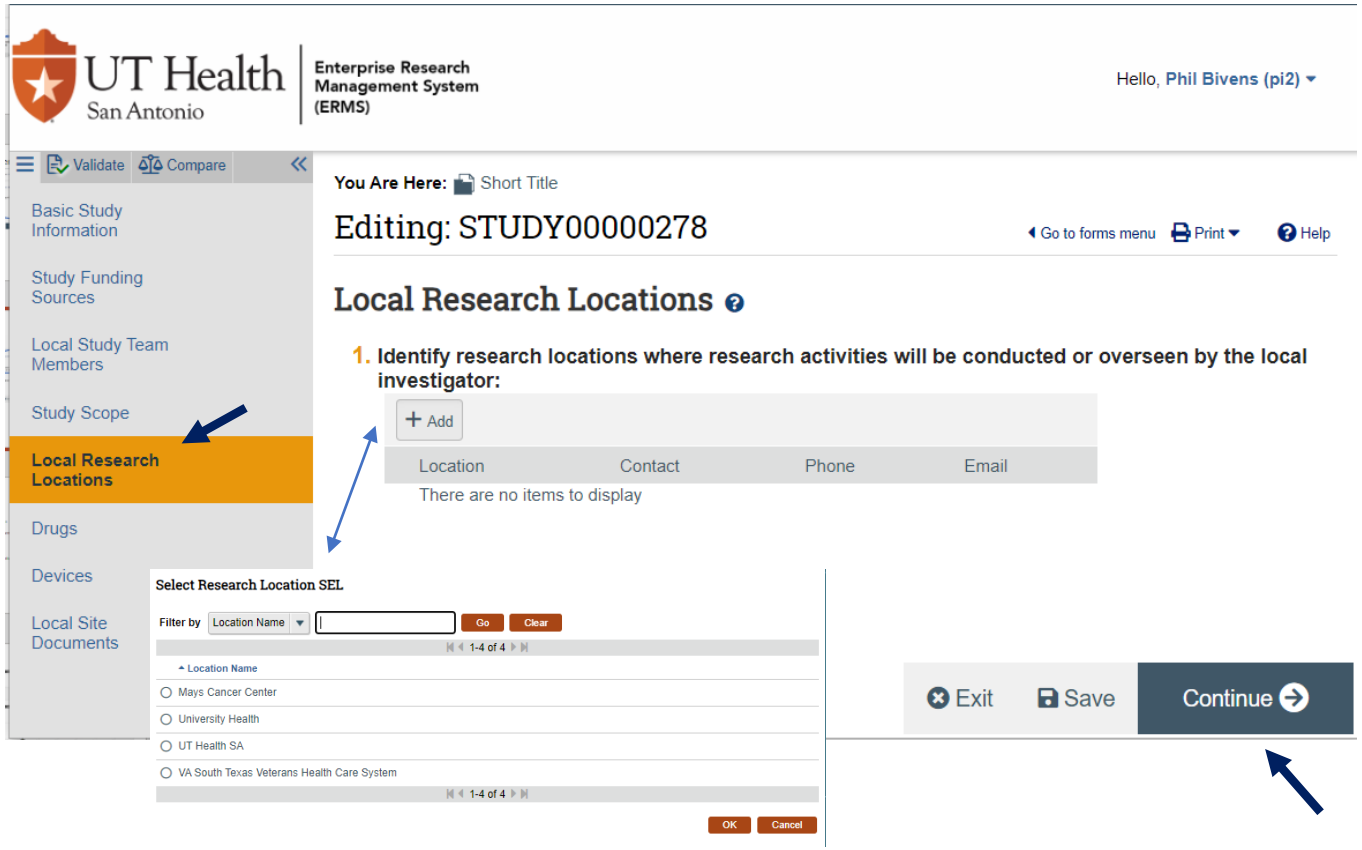
Study Scope Page (Drugs and Devices)
Answering 'Yes' will create forms for drugs and/or devices.
You can use the navigation element located on the left of the page to skip between the drugs and/or devices forms. You can also exit the form and return later to add information before submitting the study for review.

Drug or Biologic Used?
"Specify the use of" means the protocol requires one or more subjects to use the drug, biologic, dietary supplement, or food as part of study participation, regardless of whether its use is considered standard of care.

Example: If the protocol indicates that "Subjects in group 1 **will take** 650 mg of aspirin in response to a headache," the use of aspirin is specified by the protocol. In contrast, if the protocol indicates that "Subjects in group 1 **may take** 650 mg of aspirin in response to a headache," the use of aspirin is not specified by the protocol.

UT Health San Antonio | Enterprise Research Management System (ERMS)

Local Research Locations

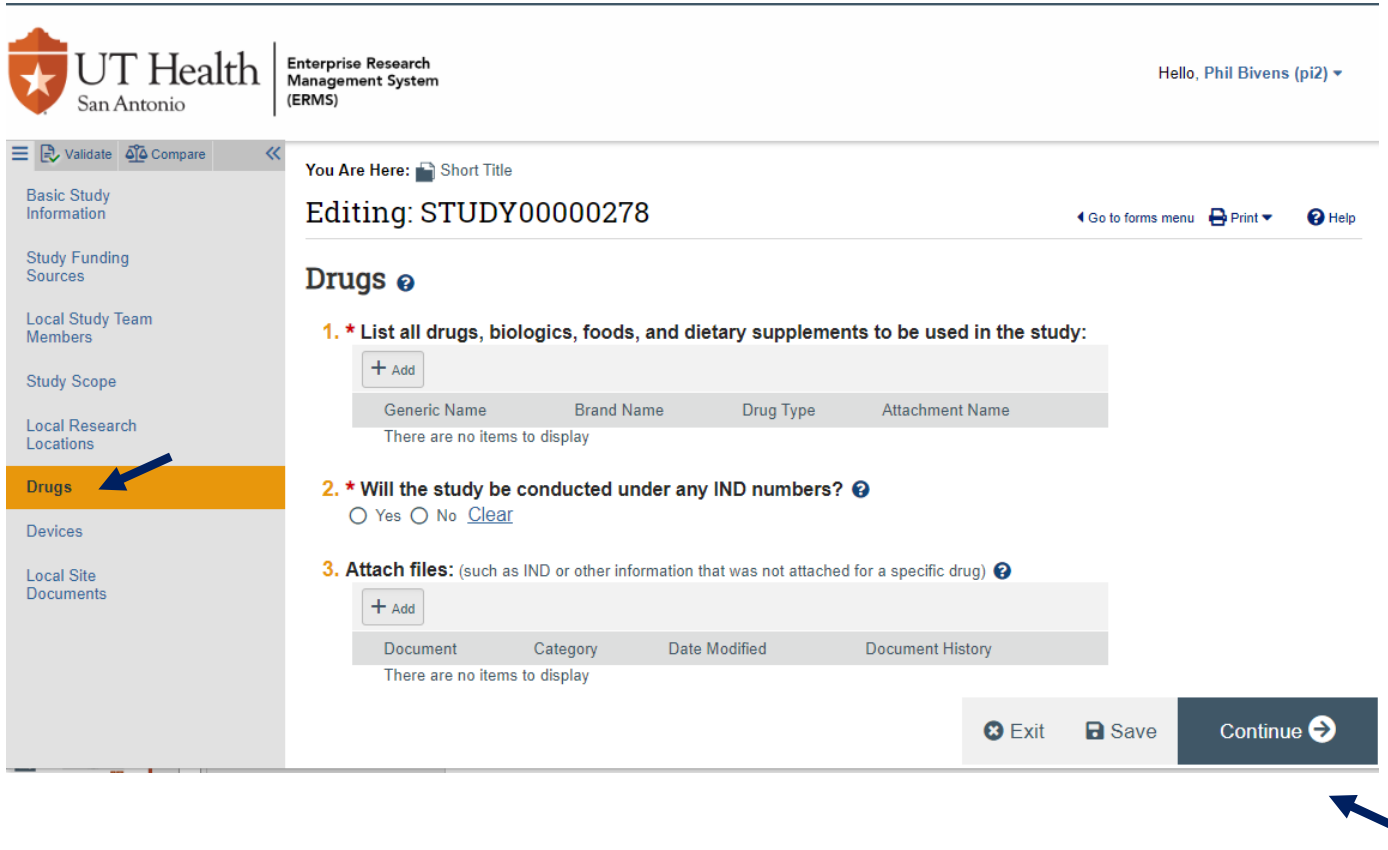


Local Research Locations Page

- Identify UT Health SA and affiliate research locations where research activities will be conducted or overseen by the local investigator (i.e., UH, VA, MCC).
- Do NOT add locations outside UT Health SA and affiliates here. Other sites under the local investigator will be added in a separate section.

UT Health San Antonio | Enterprise Research Management System (ERMS)

Drugs



Drugs Page
Identify all drugs to be used on human subjects as part of this study. Include all information the IRB needs to identify and evaluate any investigational new drug.

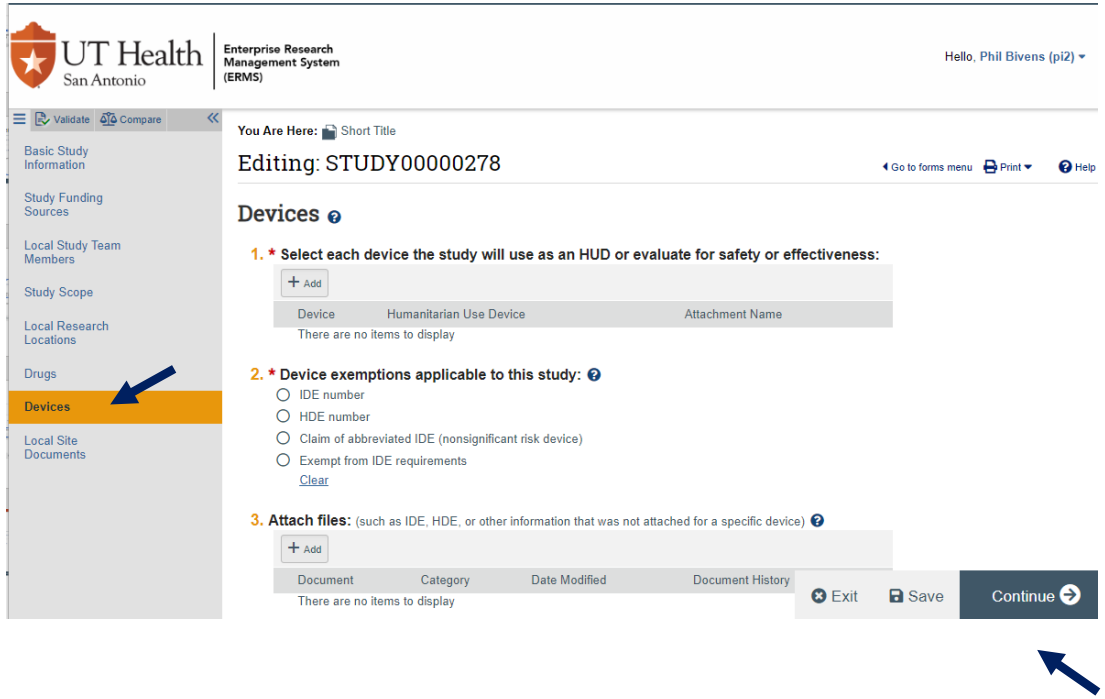
For studies being reviewed by UT Health SA IRB, an IND letter is required for all investigational drugs. Complete and upload a **Form O** for all off-label use of a drug requesting an exemption.
Include files related to this drug (i.e. package insert, investigator brochure).

Study Conducted Under IND
For studies being reviewed by UT Health SA IRB, an IND letter is required for all investigational drugs. Complete and upload a **Form O** for all off-label use of a drug requesting an exemption.

Attach Files For Drugs
Attach files related to this drug (i.e. package insert, investigator brochure). Complete and upload a **Form O** for all off-label use of a drug requesting an exemption.

UT Health San Antonio | Enterprise Research Management System (ERMS)

Devices



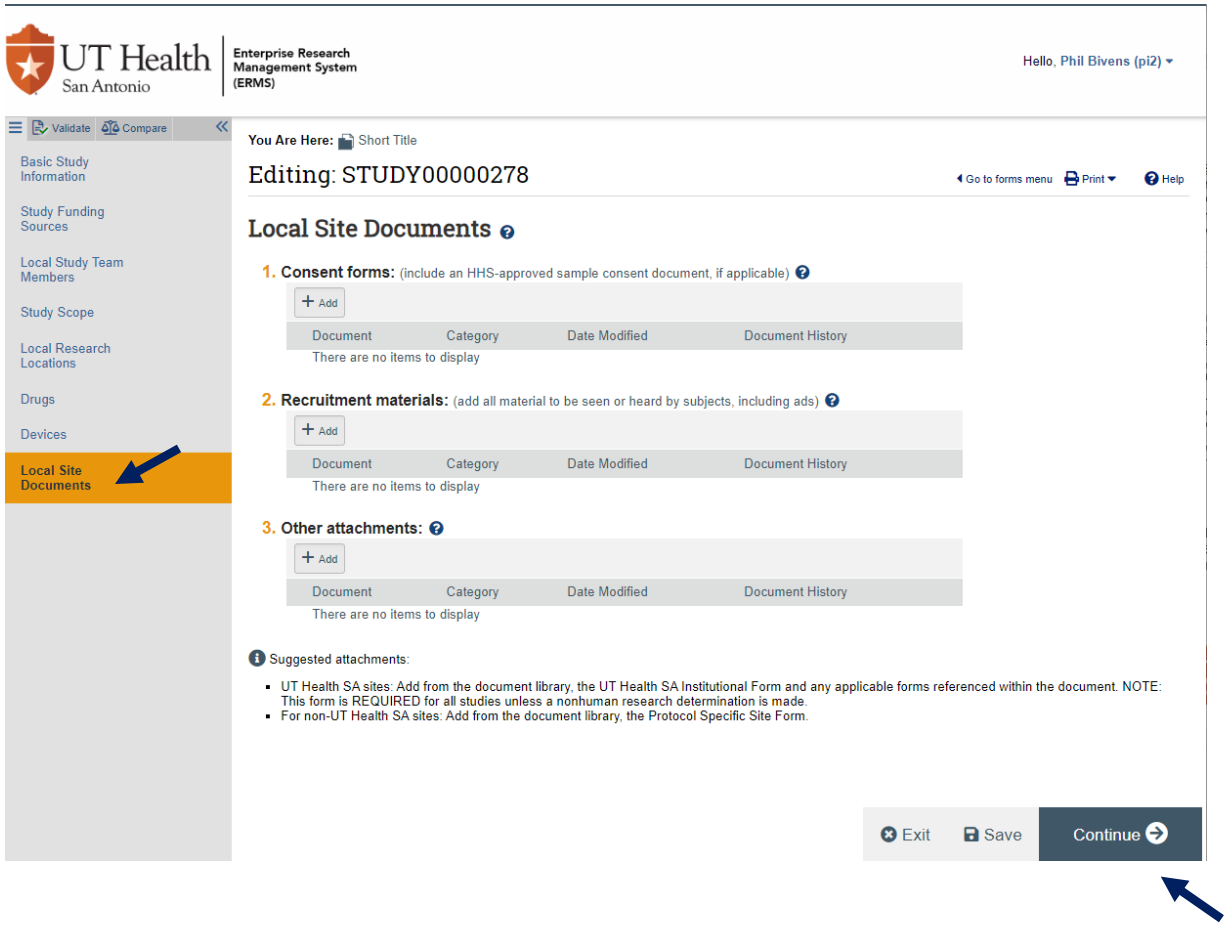
Devices Page
Identify all devices to be used as an HUD or evaluated for safety and effectiveness on human subjects as part of this study. Include all information the IRB needs to identify and evaluate any device with exemptions or claimed exemptions.
Attach files related to this device (i.e. FDA exemption status, FDA cleared labeling information, device brochure, instruction manual, or information from the manufacturer describing the device). For studies reviewed by UT Health SA IRB, a **Form P** Investigational Use of a Device must be completed and uploaded for a claim of abbreviated IDE (nonsignificant risk device) or exemption from IDE requirements.

Device Exemptions
For studies reviewed by UT Health SA IRB, a **Form P** Investigational Use of a Device must be completed and uploaded for a claim of abbreviated IDE (nonsignificant risk device) or exemption from IDE requirements.

Attach Files for Devices
For studies being reviewed by the UT Health SA IRB, a Sponsor or FDA IDE letter or FDA HDE letter is required for all investigational devices that do not meet abbreviated or exemption requirements. Complete and upload a **Form P** for all claims of abbreviated IDE (nonsignificant risk device) or exemption from IDE requests.

UT Health San Antonio | Enterprise Research Management System (ERMS)

Local Site Documents



Consent Forms
Upload site specific consent form from sponsor or utilize appropriate UT Health SA template informed consent located within the **Library.**

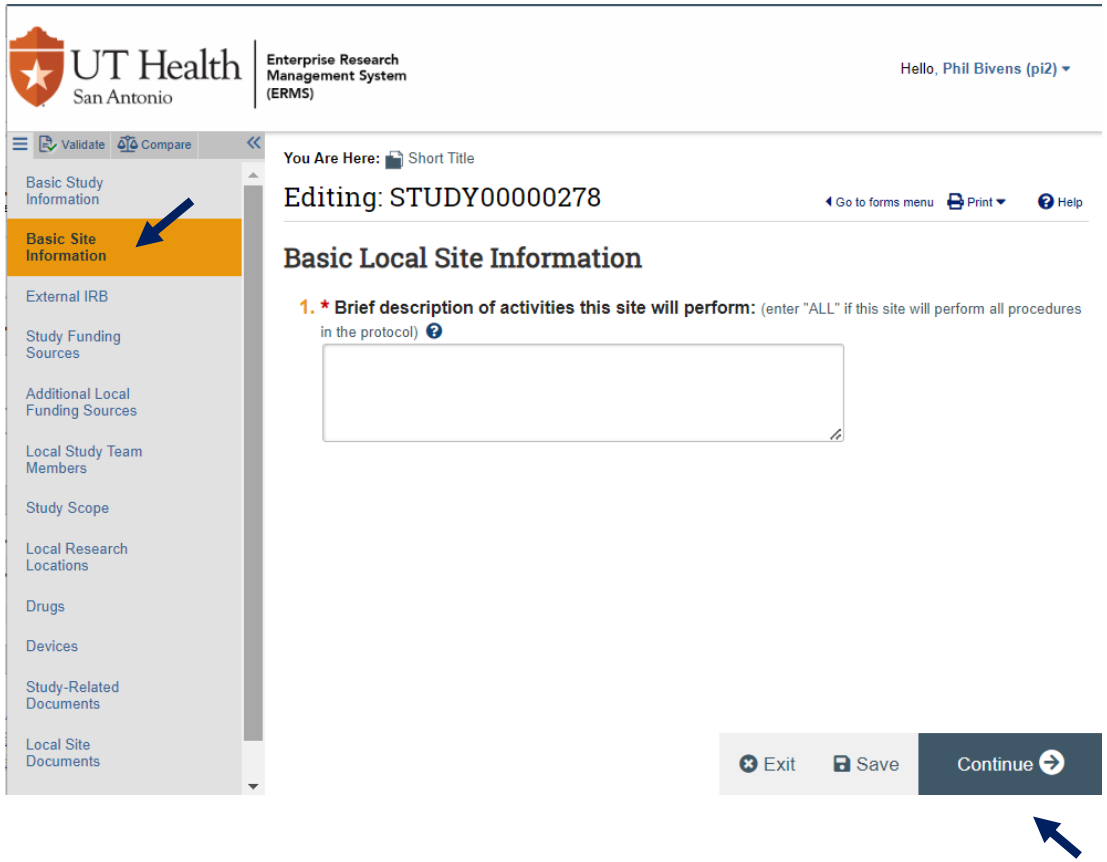
Recruitment Materials
Add all UT Health SA specific material to be seen or heard by subjects, including ads.

Other Attachments
Add the **UT Health SA Institutional Form** and **UT Health SA IRB Application** and any applicable forms referenced within the document. Forms are in the **Library** under Templates.

NOTE: The institutional form is REQUIRED for all studies unless a non-human research determination is made. The IRB application is REQUIRED for all non-exempt UT Health IRB studies.

UT Health San Antonio | Enterprise Research Management System (ERMS)

Create New Study – External IRB Reliance



Brief Description of Activities This Site Will Perform
In a few words, summarize your activities as a participating site in this multi-site or collaborative research study. If your site will be conducting all portions of the research, type “ALL.” If your site will be conducting only certain portions of the research, include a summary.

For example: This study includes both adults and children as research subjects; however, at this site, we will include only children. Therefore, we will conduct only those procedures related to children.

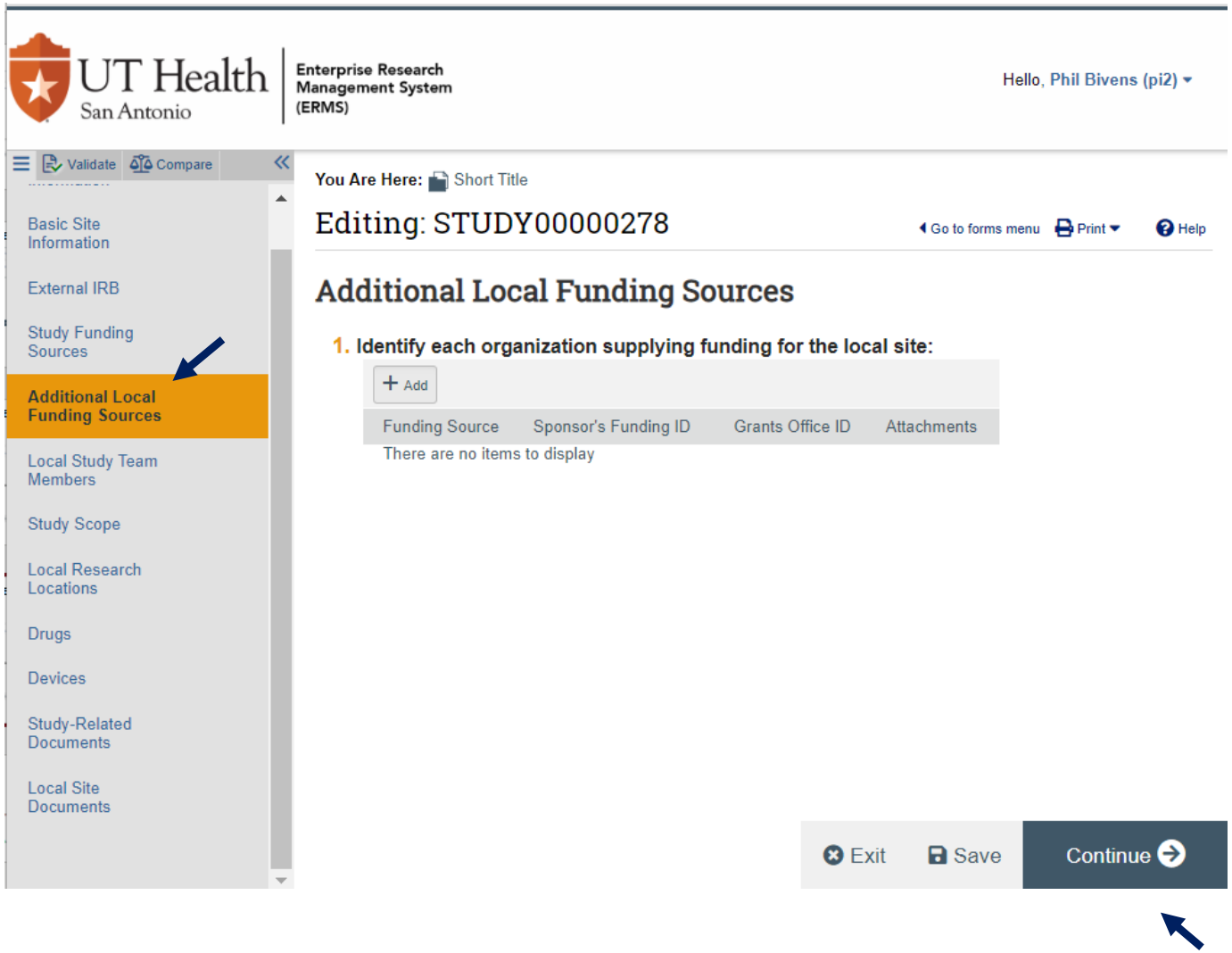
UT Health San Antonio | Enterprise Research Management System (ERMS)

External IRB

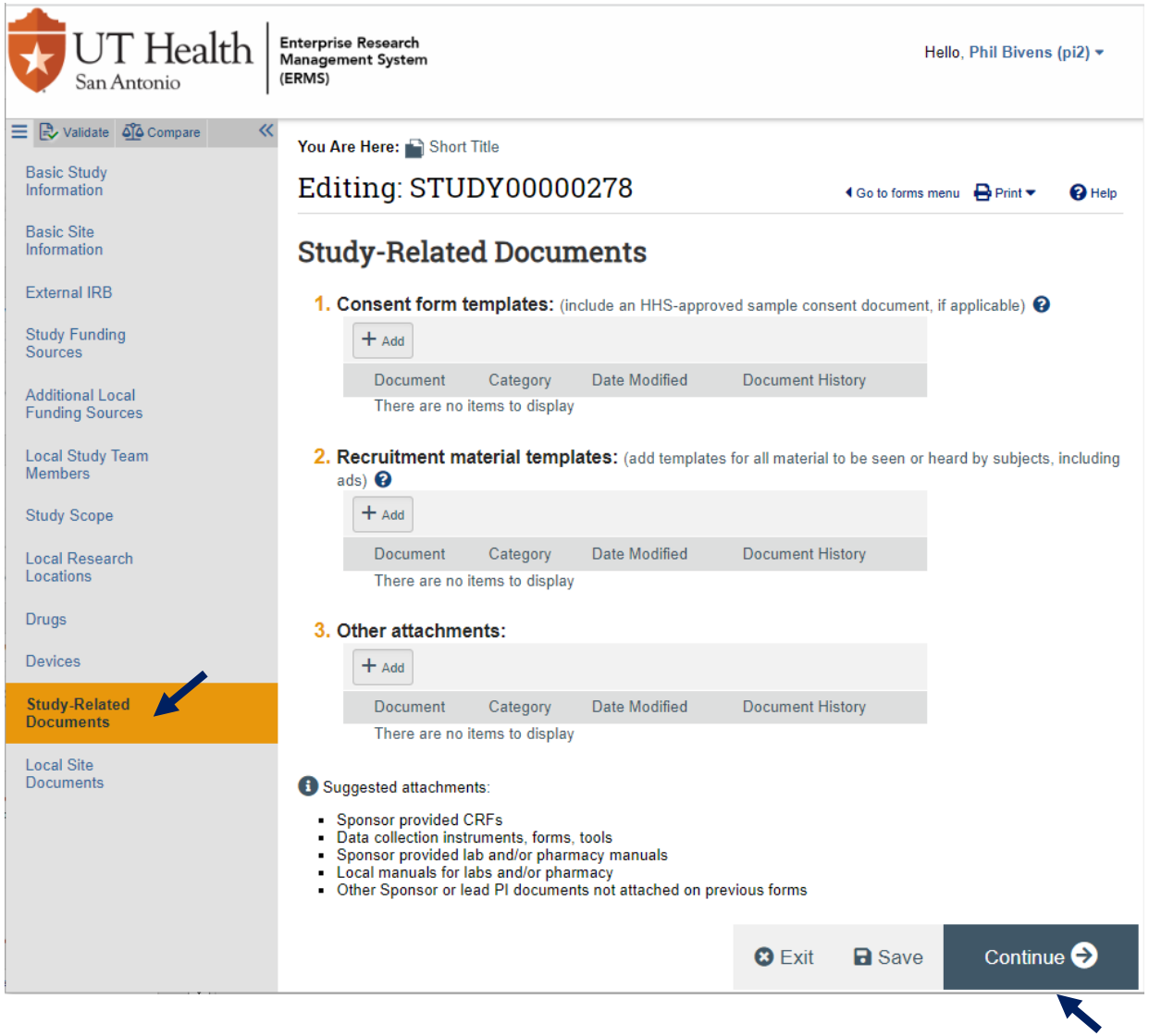
External IRB
Select the IRB outside your institution that will act as the IRB of record for this study. If you cannot find the external IRB in the list, contact IRBReliance@uthscsa.edu for assistance.

UT Health San Antonio | Enterprise Research Management System (ERMS)

Additional Local Funding Sources



Study-Related Documents



Study-Related Documents - Consent form templates

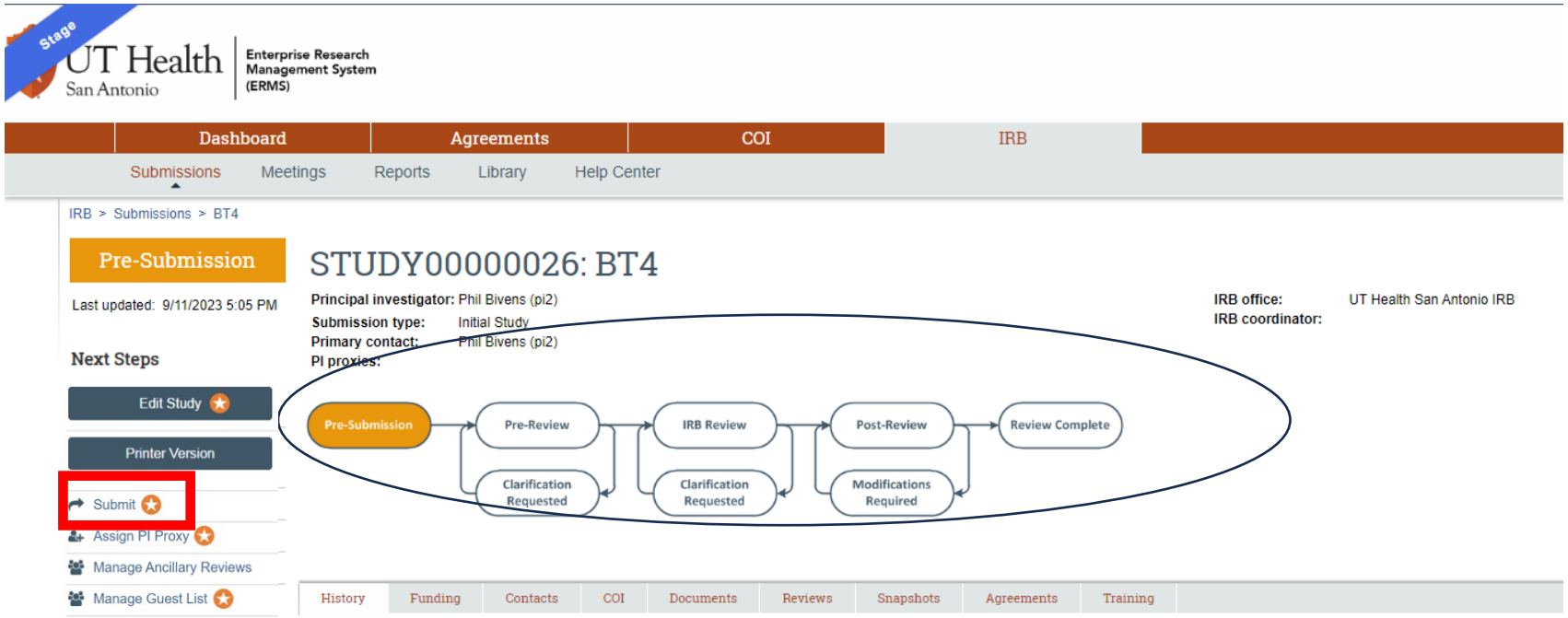
- Add sponsor or lead PI approved template(s), if available.
- Do **not** add UT Health SA specific informed consent here. It will be uploaded under Local Site Documents.

Study-Related Documents - Recruitment material templates

- Add all material to be seen or heard by subjects, including ads, provided by the sponsor or lead PI.
- Do **not** add UT Health SA specific materials here. They will be uploaded under Local Site Documents

UT Health San Antonio | Enterprise Research Management System (ERMS)

Protocol Status and Submission – UT Health SA IRB



Pre-Submission: Means you haven't submitted the study. You can open it, and then finish and submit it for review.

Pre-Review: Under review with IRB Coordinator. Study team can no longer edit study unless it is returned by IRB Coordinator for clarifications.

IRB Review: Assigned to expedited reviewer or full board meeting.

Post-Review: IRB Coordinator finalizes review.

Review Complete: Study review complete. Notification send to PI, PI Proxy, and POC.

Clarification Requested: Changes requested by the IRB Coordinator or IRB Expedited Reviewer.

Modification Required: Changes required by the convened IRB.

Edit Study

If you feel something has been incorrectly filled out, or a person was not added, this will allow you to revise your application prior to submission.

Adding a PI Proxy

This function will allow the addition of a **PI Proxy**. A **PI Proxy** has the ability to act on behalf of the PI. Only a PI or a **PI Proxy** may submit a study.

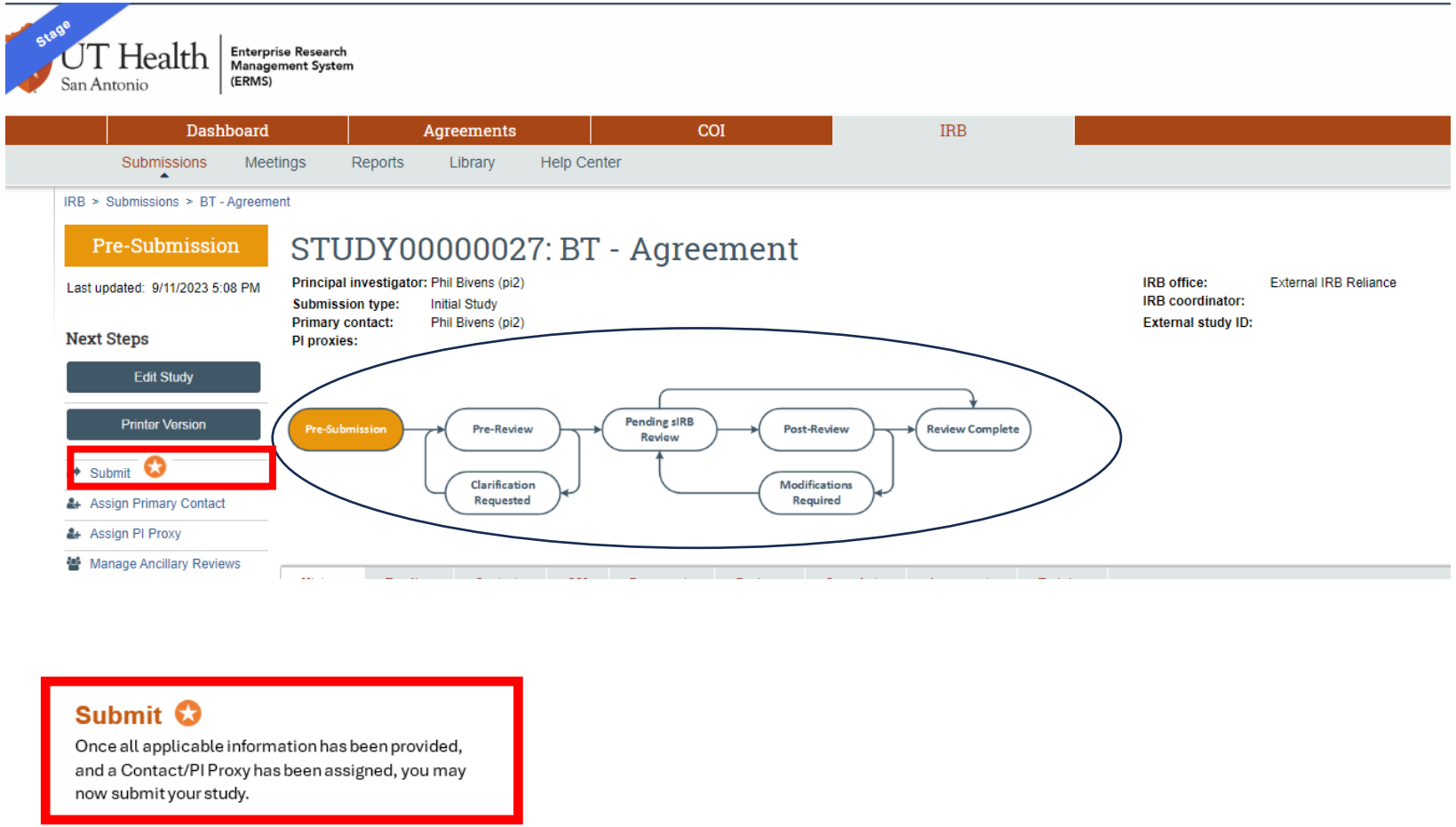
Note: If you wish to add an individual a **PI Proxy**, this person must be listed as a **Local Study Team Member**

Submit

Once all applicable information has been provided, and a Contact/PI Proxy has been assigned, you may now submit your study.

UT Health San Antonio | Enterprise Research Management System (ERMS)

Protocol Status and Submission – External IRB Reliance



Pre-Submission: Means you haven't submitted the study. You can open it, and then finish and submit it for review.

Pre-Review: Confirm reliance.

- The IRB Reliance Coordinator will confirm external IRB reliance, moving the study from the Pre-Review state to the Pending sIRB Review state.
- An email notification will be generated and sent to the PI, PI Proxy, and POC.
- A comment will be sent to the study team for pending items while awaiting sIRB review.

Pending sIRB Review: Record sIRB Decision.

- Once the sIRB makes a determination, the IRB coordinator records the sIRB determination, moving the study from the Pending sIRB Review state to the Review Complete state.

Review Complete: Study review complete. An acknowledgement letter is generated for approval to activate the study at UT Health SA after sIRB determination and all institutional requirements are met.

Clarification Requested: Changes requested by the IRB Reliance Coordinator.

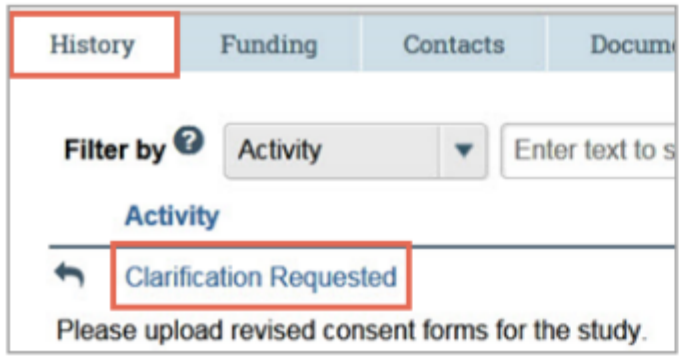
Modification Required: Will not use. Decision by sIRB will not be recorded until approved.

UT Health San Antonio | Enterprise Research Management System (ERMS)

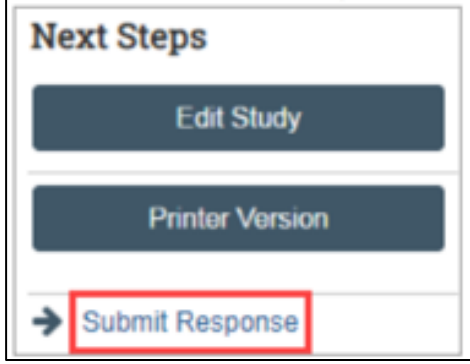
Clarifications Requested

① Click the **History** tab and review the Clarification Requested activity.

Note: If the reviewer attached a document, a link to open it appears on the History tab.

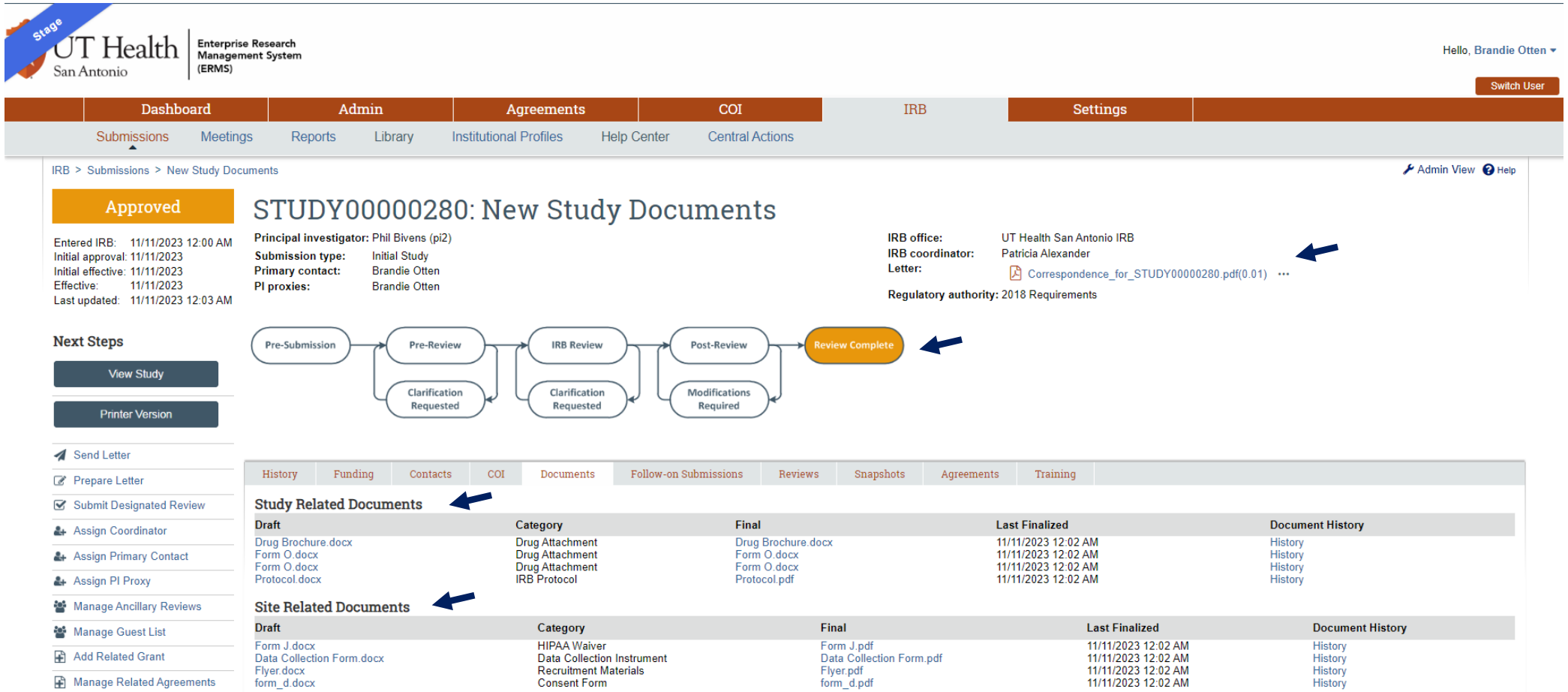


② On the submission workspace, click **Submit Response**.

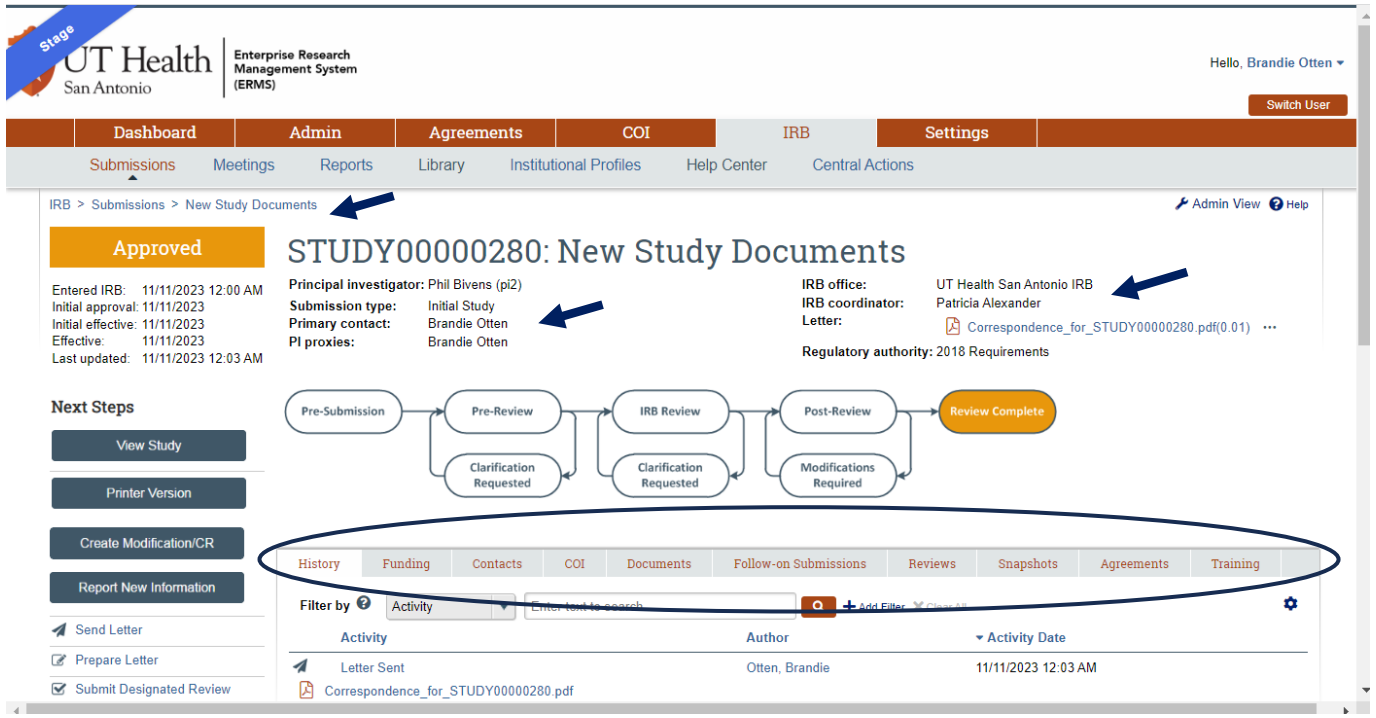


UT Health San Antonio | Enterprise Research Management System (ERMS)

Approval Documents



Study Information



History: lists the activity taken on a submission including any comments, attachments, or correspondence added.

Funding: lists funding sources and related grant information.

Contacts: lists PI, study team, and guests who can view the submission.

COI: listed related disclosure profiles.

Documents: lists study and site related documents.

Follow-on Submissions: lists continuing reviews, modifications, RNIs, and external IRB updates.

Reviews: lists ancillary reviews.

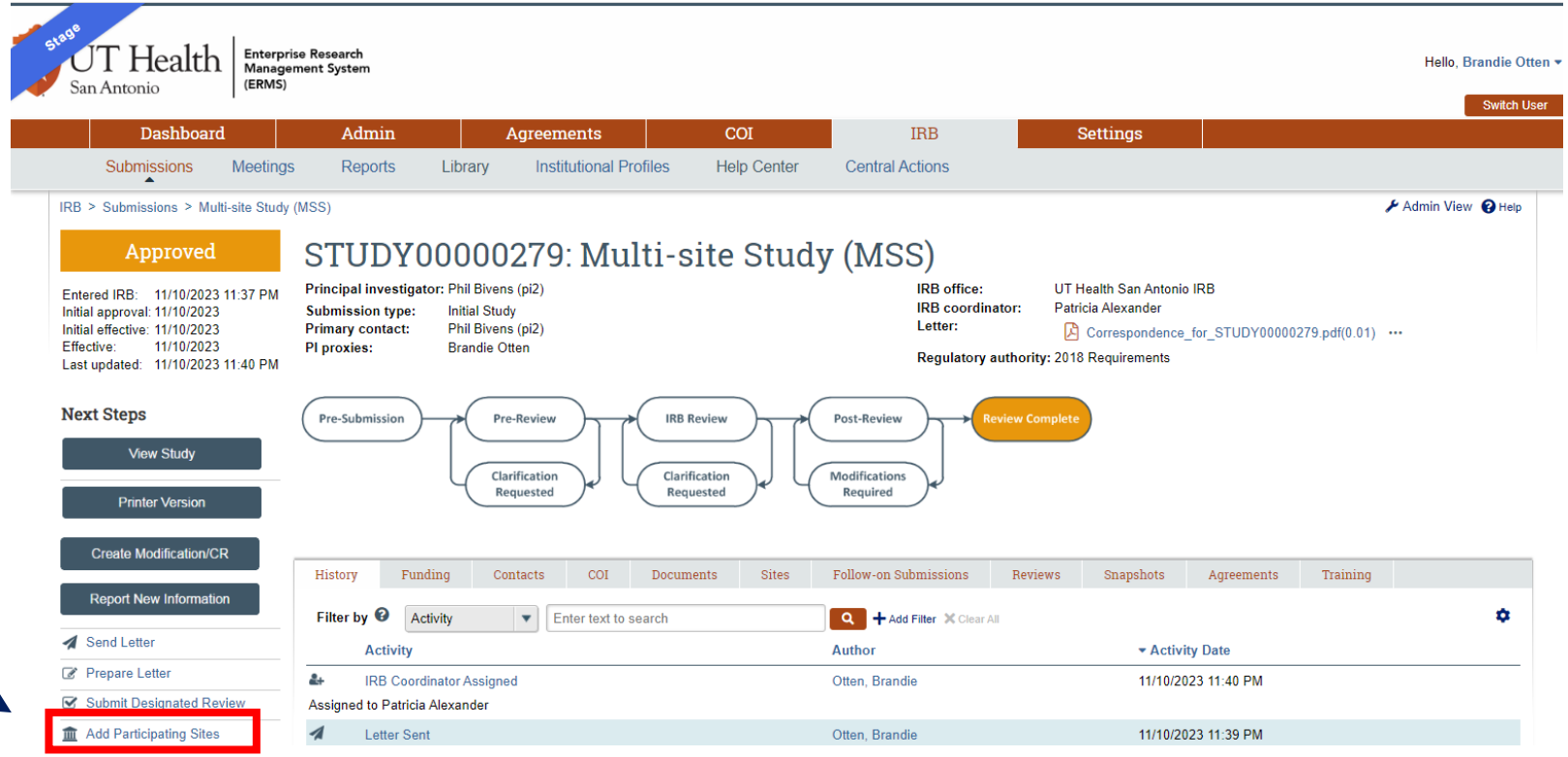
Snapshots: lists the history of submission contents.

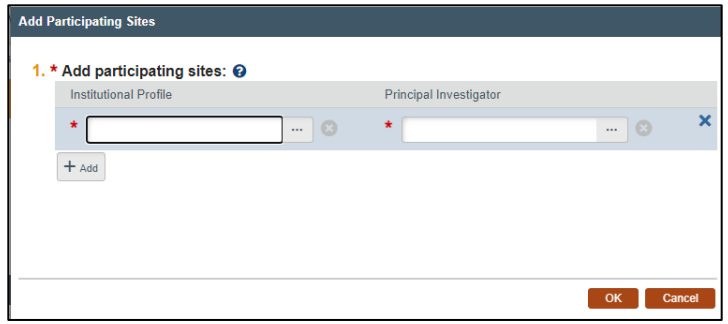
Agreements: lists related agreements.

Training: lists study team related training

UT Health San Antonio | Enterprise Research Management System (ERMS)

Add Participating Sites



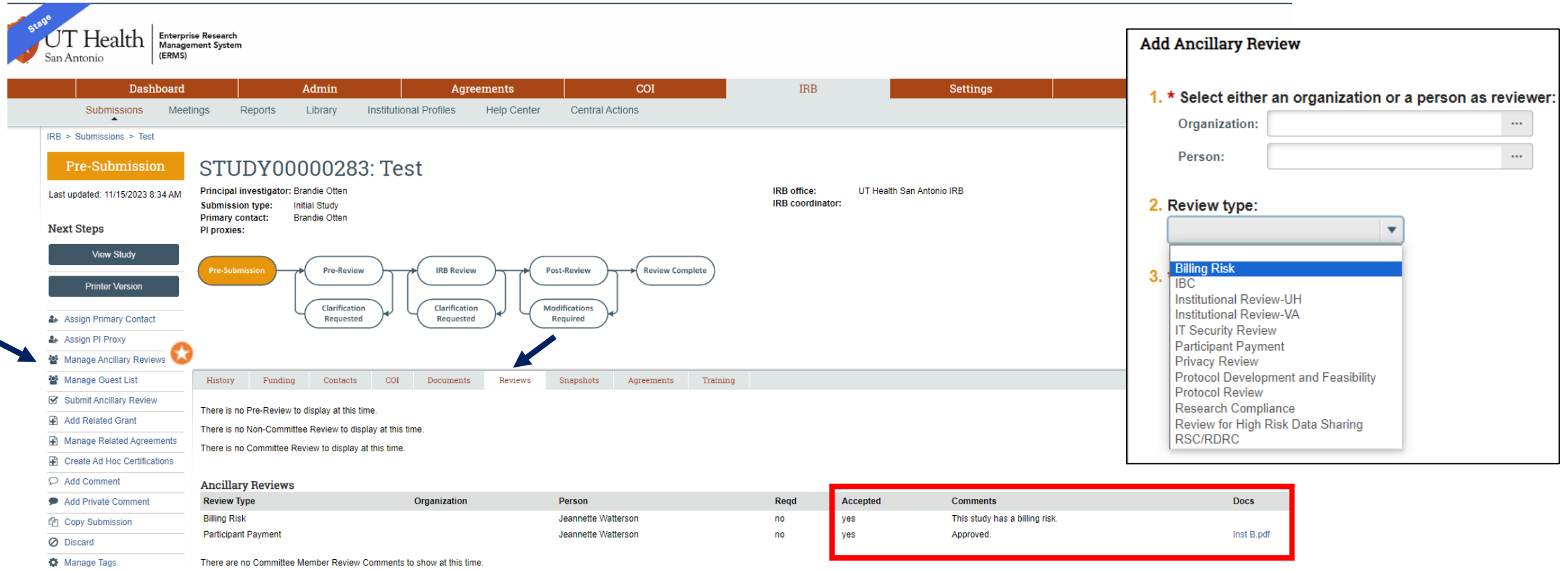


Note: IRB Coordinator will confirm site(s) and site PI(s) for selection.

Add / Manage participating sites when non-affiliated sites are relying on UT Health SA IRB as the sIRB of record.

UT Health San Antonio | Enterprise Research Management System (ERMS)

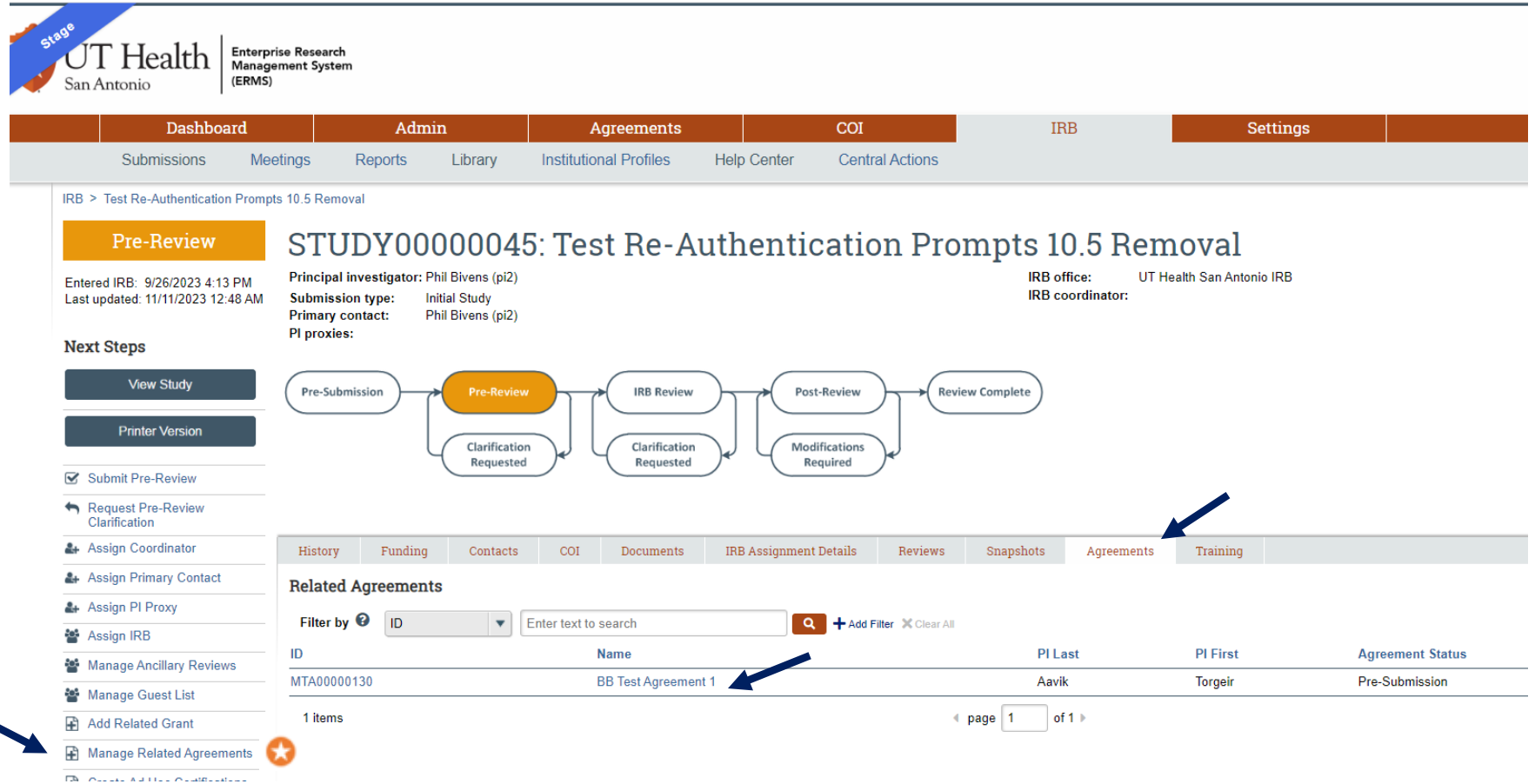
Ancillary Reviews



IRB Coordinator will add appropriate ancillary reviews even though the ‘Manage Ancillary Reviews’ button is accessible by study team.

UT Health San Antonio | Enterprise Research Management System (ERMS)

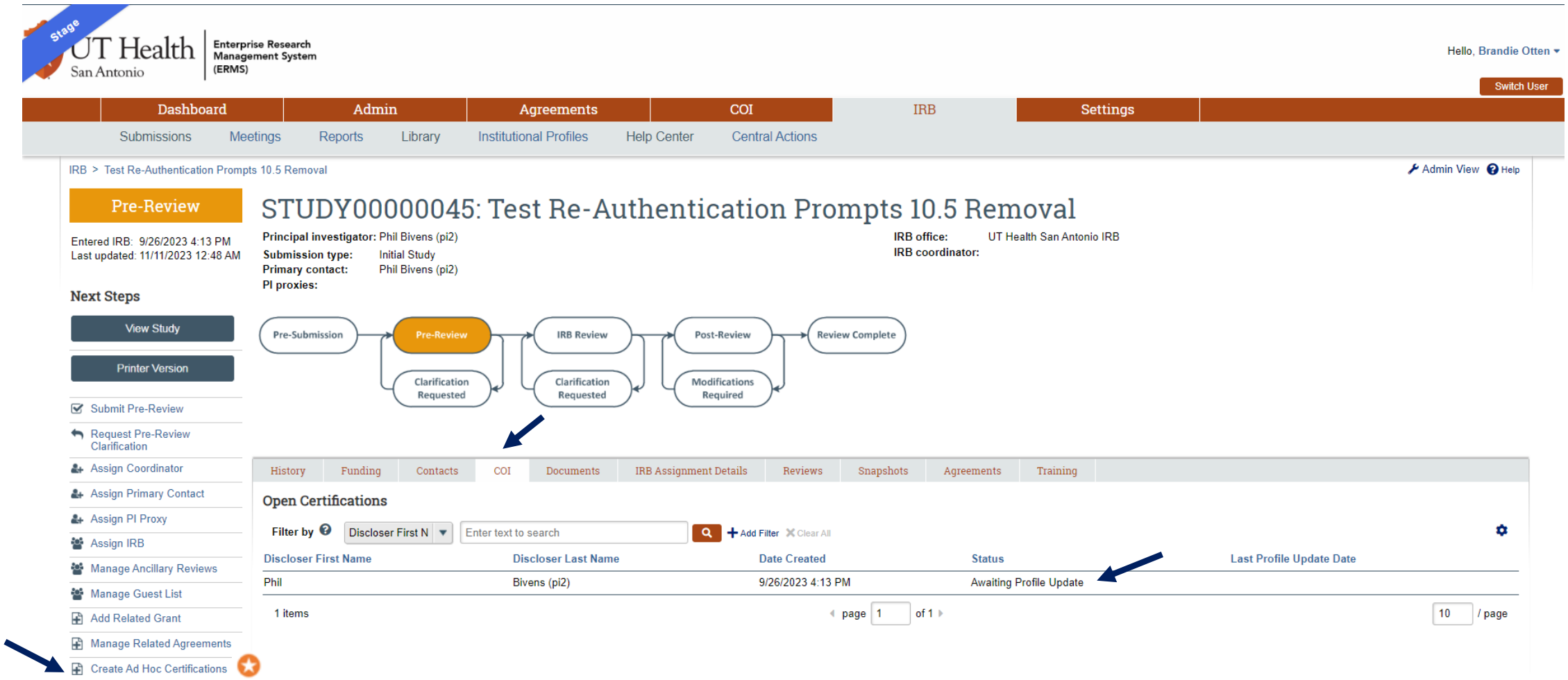
Agreements



- PI/Study Team should add appropriate linked agreements using ‘Manage Related Agreements’ button. IRB Coordinator can add later if needed.

UT Health San Antonio | Enterprise Research Management System (ERMS)

Conflict of Interest - COI

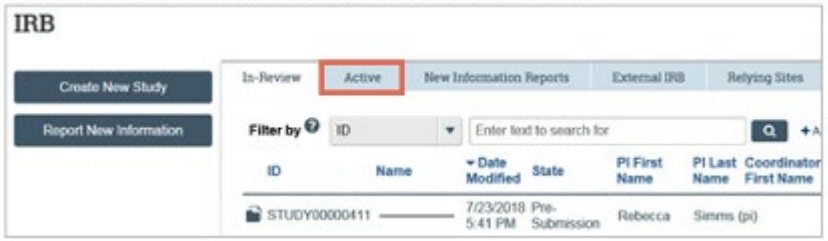


‘Create Ad Hoc Certifications’ button only viewable to IRB Coordinator.

UT Health San Antonio | Enterprise Research Management System (ERMS)

Follow-on Submissions – UT Health SA IRB

① On the IRB page, click the **Active** tab and open the approved study.



② Click the **Create Modification/CR** or **Report New Information** button.

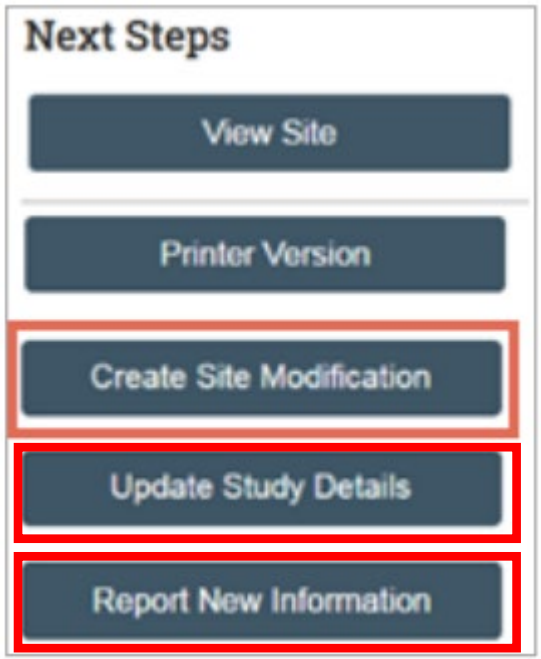
③
- Complete the pages.
- Click Continue to move through the pages and Finish on the last page.
- From the workspace, click Submit.

UT Health San Antonio | Enterprise Research Management System (ERMS)

Follow-on Submissions – External IRB Reliance

① Click the **External IRB** tab and open the study.

② Click the **Create Modification/CR** or **Report New Information** button.



③

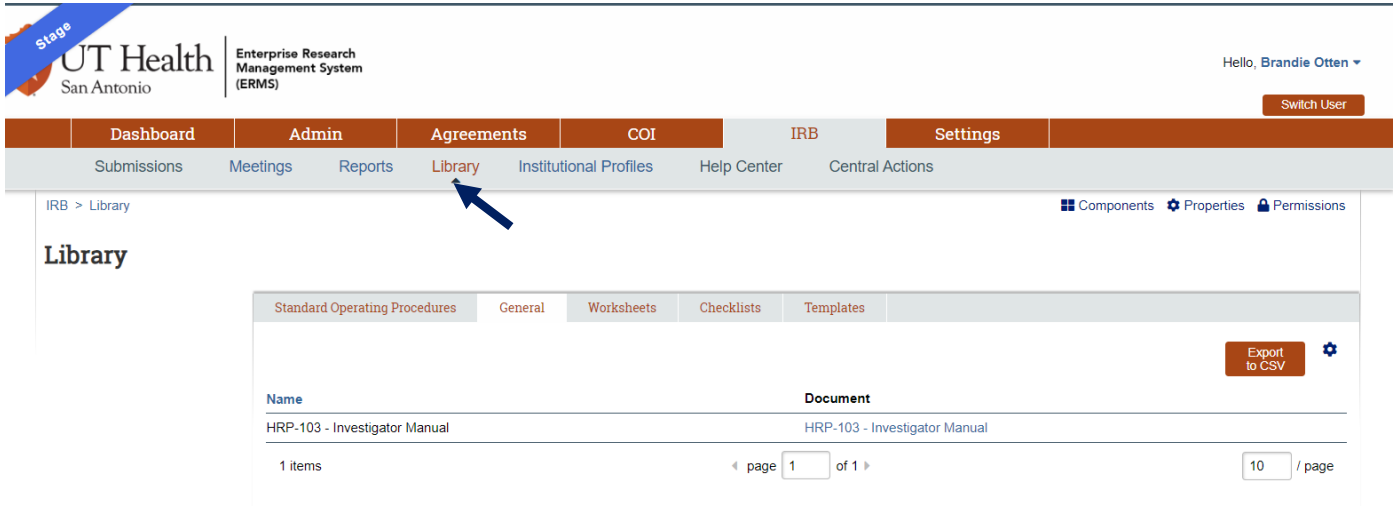
- Complete the pages.
- Click Continue to move through the pages and Finish on the last page.
- From the workspace, click Submit or Finalize Updates.

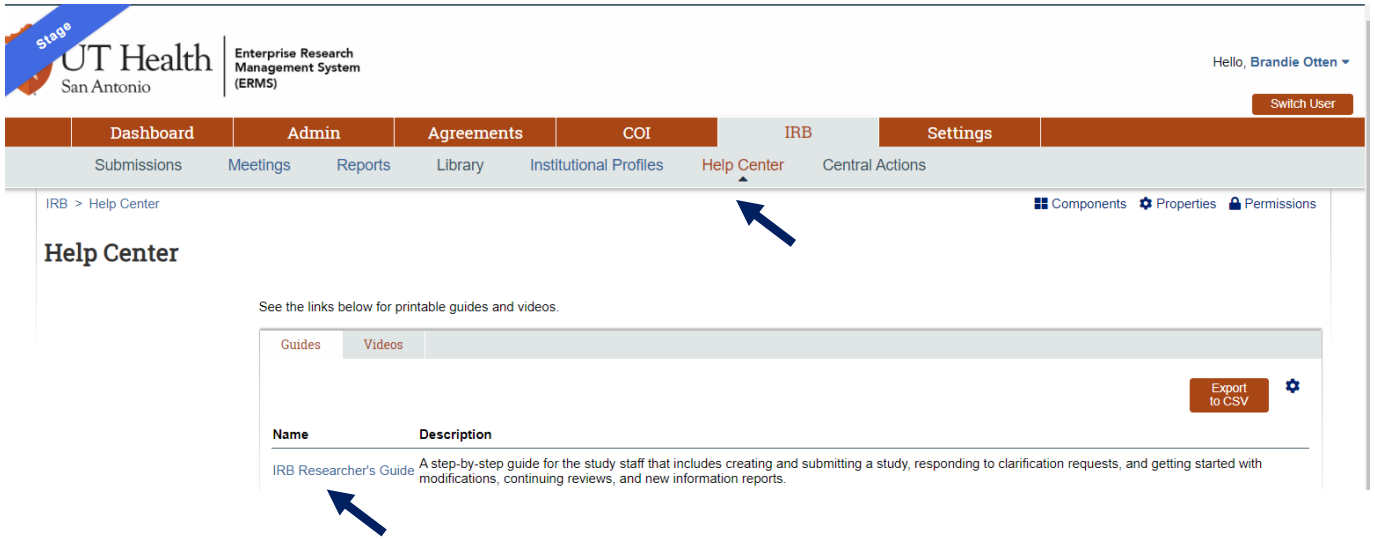
Create Site Modification: to update submission information such as a PI change that requires external IRB review.

Update Study Details: to update submission information such as a personnel change that does not require external IRB review.

UT Health San Antonio | Enterprise Research Management System (ERMS)

Library and Help Center





Standard Operating Procedures: All IRB and External IRB Reliance SOPs
General: Investigator Handbook and FAQs
Worksheets: Help documents for IRB reviewers.
Checklists: IRB reviewer determinations.
Templates: IRB submission forms and templates.

Guides: How to and Quick Start guides.
Videos: Overview of submission and/or review processes.

UT Health San Antonio | Enterprise Research Management System (ERMS)

Important Changes

- All submissions initiated in ERMS

  **previously through REDCap for clinical trials and prompt reporting or via the current email process*

- Coverage Analysis is no longer part of the IRB files
- Institutional form revised (removed ERMS questions)
- No Personnel Form (Inst M)
- No institutional activation letter for UT Health IRB studies
- Participant payment roles added to ERMS application
- All sIRB approvals and approved documents for external IRB studies submitted in ERMS

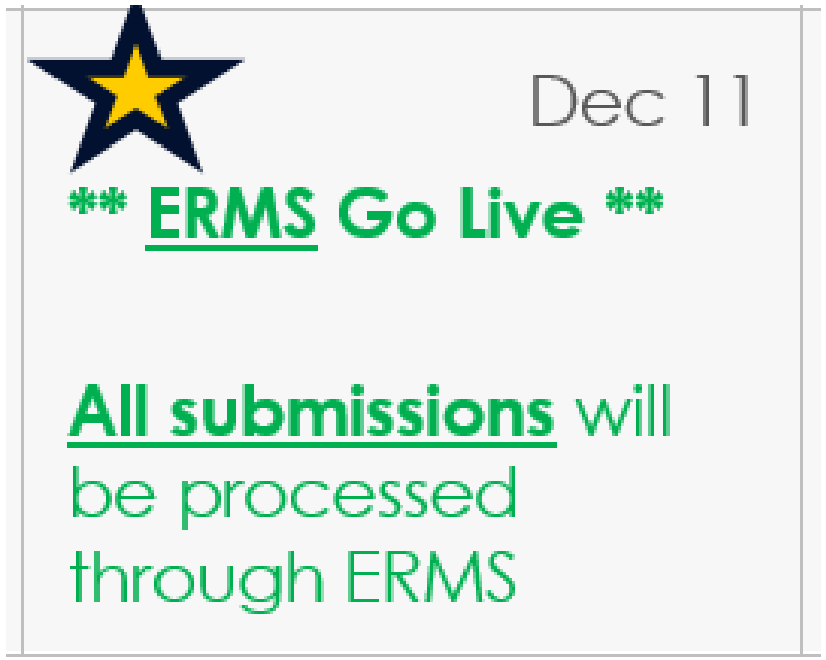
  **previously only required when involving institutional changes*

- Continuing review submission includes study closure
- ERMS requires UT single sign-on

  **previously allowed non-UT accounts*

UT Health San Antonio | Enterprise Research Management System (ERMS)

Important Deadlines



November 2023

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
19	20	21	22 Deadline for submission of all **new studies** via current email process	23 Holiday	24 Holiday	25
26	27	28	29	30		

Transition active and pending studies to ERMS *

December 2023

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
					1 Deadline for submission of **other business items** via current email process	2
3	4 **Emergency submission ONLY**	5 **Emergency submission ONLY**	6 **Emergency submission ONLY**	7 **Emergency submission ONLY**	8 **Emergency submission ONLY**	9
10	11 ** ERMS Go Live ** All submissions will be processed through ERMS	12	13	14	15	16

Transition active and pending studies to ERMS *

* Non-exempt UT Health SA IRB and external IRB studies

UT Health San Antonio | Enterprise Research Management System (ERMS)

Thank you!

Questions?

Jeannette Watterson, PhD
Director, Institutional Review Board
Office of the Vice President for Research
watterson@uthscsa.edu
210-562-8205

Brandie Otten
Associate Director, Institutional Review Board
Office of the Vice President for Research
otten@uthscsa.edu
210-567-8251

IRB@uthscsa.edu
IRBReliance@uthscsa.edu

UT Health San Antonio | Enterprise Research Management System (ERMS)